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Division of Transplantation

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Jade K. Perdue, M.P.A.
Operations and Analysis Branch, Division of Transplantation
Telephone: 301-443-3124
Fax: 301-443-6095

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I. Funding Opportunity Description

Purpose

This program guidance is provided to assist federally designated organ procurement organizations (OPOs), emergency medical systems, donor hospitals and other private nonprofit or public entities eligible for funds under Section 377A(b) of the Public Health Service (PHS) Act, as amended (42 U.S.C. 274f-1) to prepare Fiscal Year (FY) 2007 applications for Federal funds for the extramural grant program, Clinical Interventions to Increase Organ Procurement (CIOP). This extramural grant program is administered by the Division of Transplantation (DoT), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services (HHS).

This program will provide support for the implementation and evaluation of highly promising strategies and approaches that can serve as model interventions for increasing organ donation from uncontrolled donors after cardiac death (UDCD). The ultimate goal of this grant program is to increase the donation of solid organs (e.g. kidney, liver, and lung) and substantially increase the availability of transplantable organs in the United States. The specific intent of this program is to support applied research efforts to: i) improve clinical techniques for obtaining and using organs from UDCD, ii) evaluate suitability of organs to be procured from UDCD organs, and iii) optimize likely outcomes and increase clinical acceptance of UDCD.

For purposes of this program, model interventions are defined as those that are: (1) effective in producing a verifiable and demonstrable impact on organ procurement and transplantation, (2) replicable, (3) transferable, and (4) feasible in practice. All projects must have rigorous scientific methodology, and evaluation components capable of ascertaining the effectiveness of the intervention.

Applications may focus on a single or multi-site pilot project or replication of interventions already shown to be effective in a pilot study. With the latter, findings supporting the effectiveness of the original intervention must be provided. Development of intervention(s) may be supported by the grant but shall be limited to no more than 25 percent of project funding and staff time. Applicants have considerable flexibility in proposing the intervention, including but not limited to: the focus and nature of the intervention, intervention site(s), geographic location(s) etc.

This grant is focused solely on clinical interventions to increase UDCD. Funds will not be used for other types of projects. Examples of activities that will not be supported under this program are: donation after brain death, living donation, research using animals, long term transplantation outcomes research; interventions to increase tissue donation alone, practices related to the pronouncement of death, technologies that are not fully developed or do not have sufficient benchmarking and interventions inconsistent with Federal law or statute. Projects falling within the scope of DoT's grant program, "*Social and Behavioral Interventions to Increase Organ and Tissue Donation*" described below, are also not eligible to receive funding under the Clinical Interventions Grant Program.

Social and Behavioral Interventions to Increase Organ and Tissue Donation (SBITD): The Division of Transplantation sponsors another grant program that focuses on interventions to increase organ donation from deceased and/or living donors. Applicants who are interested in the social and behavioral strategies for increasing organ donation are encouraged to review the announcement for the SBITD program that is also available at <http://www.grants.gov>. The SBITD program includes projects that investigate factors relevant to consent in cases of donation after brain death. Acceptable projects may focus on the effectiveness of donor hospital protocol and policies or public and professional education, as they affect family consent for donation. Additionally, projects may focus on the effectiveness of donor registries.

Performance Measures

Rigorous evaluation protocols to assess outcomes of the intervention must be included as a key element of all proposed projects. Intervention outcomes must be defined as the effectiveness of the intervention in improving organ procurement as defined by an increase in one of the following parameters: (1) number of UDCD organs procured and/or (2) number of UDCD organs (e.g. kidney, liver, and lung) transplanted. Because it is recognized that interventions intended to optimize organ procurement also must be assessed in terms of post-transplant graft survival, a portion of the proposed intervention's funding may be dedicated to assessing the interventions effectiveness in maintaining short-term (e.g., less than 6 months) graft survival rates. Projects intended solely to improve graft survival rate will not be accepted.

Background

Transplantation is the therapy of choice and often the only choice to treat conditions that have resulted in life-threatening end-stage-organ failure. Over the past two decades, advances in surgical techniques and post-transplant therapies have improved both short- and long-term graft survival. On-going and future research will continue to contribute to overcoming some of the remaining medical and biological obstacles. However, even if these obstacles are overcome, the growing number of individuals needing transplants and the inadequate number of organ donors may remain major barriers to providing this life-saving and life enhancing treatment for all who need it. On average, approximately 12,000 brain deaths per year could result in organ donation; however, in 2005 only 7,593 brain deaths resulted in donation. Even with a national organ per donor average of approximately 3 organs per deceased donor and with the contributions of 6,895 living donors, only 28,108 patients received transplants in the United States in 2005, while 7,170 individuals died waiting. One area that potentially offers hope of expanding this limited pool of donors is that of UDCD.

An Institute of Medicine Report, *Organ Donation, Opportunities for Action*, published in 2006 by the National Academies of Science, Washington, D.C., cites a conservative estimate of 22,000 people per year who die due to cardiac arrest and who would meet the Modified Madrid Criteria for organ donation. Uncontrolled or unexpected death occurs in circumstances in which cardiopulmonary function ceases spontaneously, often with death occurring in an unanticipated fashion, frequently outside the hospital setting or in a situation

in which less is known about the viability of the organs; these deaths often involve the loss of circulatory function before the neurologic determination of death or brain death.

Over the past three years there has been considerable attention given to and progress made with regards to maximizing donors after cardiac death (DCD). HRSA/DoT is committed to increasing donation and transplantation rates from DCD donors and has placed DCD within their strategic plan and program goals. To that end, the Organ Donation and Transplantation Collaboratives have focused on increasing acceptance of DCD across the country. The Collaboratives have identified best practices related to consent, logistics, donor management and procurement in DCD cases. As a result, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), which participates in the Collaboratives' Leadership Coordinating Council (LCC), has required that each hospital have a DCD policy in place by January 1, 2007. Of note, is that more and more of the donation community is becoming skilled at DCD, so much so that since 2003 there has been a 250% increase in the number of organs procured from this type of donor. Logically, as stated in the IOM Report, *Opportunities for Action*, those organ procurement organizations and corresponding donation service area (DSA) partners are well positioned to explore UDCD.

The Clinical Interventions for Increasing Organ Procurement was originally launched in 2002 and has awarded 11 projects to date totaling \$11 million. In the past, the focus has been on procuring all medically suitable consented and medically appropriate organs from brain dead and DCD donors. Interventions could have focused on hemodynamic stability after brain death, and/or improving organ donor evaluation practices. This is the first year that the clinical focus will be solely on UDCDs.

Several resources of potential interest to applicants are:

- “Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement” (<http://www.nap.edu/catalog/6036.html>);
- “Non-Heart-Beating Organ Transplantation: Practice and Protocols” (<http://www.nap.edu/catalog/9700.html>);
- “Organ Donation, Opportunities for Action” (<http://newton.nap.edu/catalog/11643.html>)

All three resources are available to read online at no cost, or can be purchased in paperback from the National Academies Press.

Award Information

1. Type of Award

Funding will be provided in the form of a grant.

2. Summary of Funding

The estimated total funds available for the first year of support (direct and indirect costs) for all awards made under this grant program in FY 2007 will be up to \$1,000,000 for approximately three to four (3-4) projects. It is anticipated that the average award for each project year will be \$250,000-\$350,000. It is recognized, however, that budgets may vary

with project reach and complexity. Awards to support projects beyond the first year will be contingent upon the availability of appropriated funds, satisfactory progress, and a determination that continued funding is in the best interest of the Federal Government. The total project period for applications submitted in response to this program announcement may not exceed three (3) years. The anticipated start and end dates for the first year awards are September 1, 2007 to August 31, 2008.

III. Eligibility Information

1. Eligible Applicants

This grant program seeks to promote opportunities to implement and evaluate clinical processes and practices believed to result in an increased number of organ donors and/or transplantable organs from UDCD donors. Interventions must be conducted by a consortium comprised of at least two organizations, one with a vested interest in donation and transplantation and the other a research related organization. Eligible applicants may include federally designated organ procurement organizations (OPOs), emergency medical systems, donor hospitals and other private nonprofit or public entities eligible for funds under Section 377A(b) of the Public Health Service (PHS) Act, as amended (42 U.S.C. 274f-1). Faith-based and community organizations are eligible to apply if otherwise eligible. Applications must include consortium agreements.

a. Documentation of non-profit and/or public status.

Documentation of nonprofit or public status of the applicant institution must be included in the application. Applications that fail to meet eligibility criteria will not be considered in this competition, and will be returned without review.

Any of the following constitutes acceptable proof of nonprofit status:

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

The following constitutes acceptable proof of public status:

- a. A signed statement on official letterhead by an official authorized to apply for grant funds on behalf of the public entity shall suffice.

b. Consortium

This grant program seeks to promote greater collaboration among the donation/transplantation community, and other organizations with potential to encourage UDCD donation, and organizations with research expertise and experience. Therefore, the program requires each application to be submitted by a consortium of project-relevant organizations to ensure the breadth of expertise required for the successful design, implementation, and evaluation of the proposed intervention(s). Applications submitted from single institutions that are not part of a consortium will not be accepted for review or considered for award. Consortium members must be organizations rather than individuals. The project is the responsibility of the consortium, not of an individual organization, and all major decisions shall be made by the consortium. Each consortium member must demonstrate a substantive role and substantial participation in the project. The role of each consortium member shall be reflected in the budget, project design, and staffing sections. Only organizations for which separate budgets have been submitted for each project year shall be considered consortium members. If any organization does not meet consortium requirements, *including submission of a separate budget*, that organization shall not be considered in determining whether the application meets eligibility requirements.

Supporting tasks such as providing general suggestions, reviewing plans, and supplying materials do not in themselves justify consortium status. Although such supporting tasks by relevant organizations can be very helpful, each consortium member must play a key role in the project. Applications must clearly describe the substantive role and project tasks for each consortium member. Organizations providing supporting tasks, thus not meeting consortium status, may be considered subcontractors or consultants. Individuals also may serve as subcontractors/consultants. Institutions serving as project implementation sites should not be considered consortium members unless they also have a substantive role in project design, staffing, and budget.

A consortium agreement for each consortium member shall be included in the application. A consortium agreement is a letter of commitment on the consortium member's letterhead outlining its role in the proposed project including expected contribution in staff hours and commensurate funding. A letter indicating only interest or ideological "support" does not constitute a Consortium Agreement. Organizations not submitting consortium agreements will not be considered by HRSA as consortium members.

In building the consortium, careful consideration should be given to the number of member organizations. Based upon the experience of previous grantees, a consortium of two to four organizations seems optimal. The application must include for each consortium member organization a budget for each project year. A consolidated budget combining all consortium members for each project year also must be included. While the consortium may contain any number of relevant members, it must consist at a minimum of the following two types of organizations:

- 1) at least one organization/institution with demonstrated expertise and experience in clinical research; and
- 2) at least one organization/institution currently involved in donation or transplantation. Some examples include an OPO, hospital, or other health care facility; national or

regional association; community-based service organization; or public health or other government agencies.

All consortium members and primary applicant institutions that are OPTN members (and that also are organ procurement organizations or transplant hospitals) must be in compliance with all OPTN Data submission policies. Data must be submitted in accordance with section 121.11(b) (2) of the final rule governing the operation of the OPTN, 42 CFR 121.11(b)(2). This includes existing data submissions and maintaining data compliance for the performance period of this grant.

Consortium Membership and Grant Project Activities: For each consortium member describe in 1 or 2 sentences its role in the implementation of the project's intervention. Include: name of the consortium member, key representative with contact information, and area of expertise.

c. Primary Applicant Institution

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

According to Section 377A (b) of the PHS Act, (42 U.S.C 274f-1(b)), qualified OPOs and public or other nonprofit private entities are eligible to apply as the primary applicant institution. Documentation of nonprofit or public status shall be included with Consortium Agreement for the primary applicant institution. For-profit organizations are encouraged to participate as consortium members but are not eligible to apply as the primary applicant institution.

d. Principal Investigator

The consortium shall be headed by a single principal investigator (PI) who will be scientifically and administratively responsible for the project, including oversight of all consortium-related activities. The PI must have experience and expertise relevant to the objectives of this grant program in one or both of the following areas:

- 1) design and implementation of interventions to increase donation/transplantation and/or
- 2) design and conduct of evaluation studies to assess the effectiveness of clinical interventions.

The PI must have a substantive and substantial role in the project. Women, minorities, and persons with disabilities are encouraged to apply as principal investigators. It is recommended, but not required, that the PI be an employee of the primary applicant

institution. A PI who is not employed by the primary applicant institution must meet both of the following criteria:

- 1) be employed by a public or private, nonprofit institution, and
- 2) hold a position of influence in the primary applicant institution, such as officer or board member.

e. Principal Researcher/Evaluator

The research consortium member organization shall be represented by a principal researcher/evaluator who has primary responsibility for design and conduct of the project evaluation component. This professional must have expertise in clinical research/evaluation as demonstrated by professional experience, education, and relevant publications. The principal researcher or an additional member of the research team must demonstrate education and expertise sufficient to conduct statistical analysis consistent with the proposed intervention and evaluation. Additional researchers/evaluators, not representing a consortium organization, may participate in the project in the capacity of subcontractors or consultants.

2. Cost Sharing/Matching

Applicants are not required to match or share in project costs if an award is made. However, projects that supplement government funding with in-kind contributions are encouraged. In addition, applicants may use their own funds to increase the capacity of the project.

Applicants should clearly identify which budget items are to be supported by the Federal grant and which are to be supported by in-kind contributions and/or other funding sources together with an estimate of the value of these non-federal funding sources.

3. Other

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

Maintenance of Effort

Grant funds shall not be used to take place of current funding for activities described in the application. Grant funds shall not be used to support activities that are a normal part of the organization's operations or those charges covered already by another payer, such as Medicare, Medicaid or private insurer.

IV. Application and Submission Information

1. Address to Request Application Package

Application Materials and Required Electronic Submission

The application and submission process has changed significantly. HRSA is **requiring** applicants for this funding opportunity to apply electronically through Grants.gov. All applicants **must** submit in this manner unless the applicant is granted a written exemption from this requirement *in advance* by the Director of HRSA's Division of Grants Policy. Applicants must request an exemption in writing from:

DGPClearances@hrsa.gov

Applicants must provide details as to why they are technologically unable to submit electronically through the Grant.gov portal and must provide the program's grant announcement number. As indicated in this guidance, HRSA and its Grants Application Center (GAC) will only accept paper applications from applicants that received *prior* written approval.

Refer to this guidance's Appendix A (*HRSA's Electronic Submission User Guide*) for detailed application and submission instructions. Pay particular attention to Section 3, which provides detailed information on the competitive application and submission process.

Applicants must submit proposals according to the instructions in Appendix A (*HRSA's Electronic Submission User Guide*), using this guidance in conjunction with Standard Form 424 Research and Related (SF 424 R&R). These forms contain additional general information and instructions for grant applications, proposal narratives, and budgets. These forms may be obtained from the following sites by:

(1) Downloading from <http://www.hrsa.gov/grants/forms.htm>

or

(2) Contacting the HRSA Grants Application Center at:

The Legin Group, Inc.
910 Clopper Road, Suite 155 South
Gaithersburg, MD 20878
Telephone: 877-477-2123
HRSA_GAC@hrsa.gov

Instructions for preparing portions of the application that must accompany SF 424 R&R appear in the "Application Format" section below.

2. Content and Form of Application Submission

Application Format – Requirements

See Appendix A (*HRSA's Electronic Submission User Guide*), Section 4 for detailed application submission instructions. These instructions must be followed.

The total size of all uploaded files may not exceed the equivalent of 80 pages when printed by HRSA, approximately 10 MB. This 80-page limit includes the abstract, project and budget narratives, appendices and other attachments, including consortium agreements and letters of support. Standard forms are NOT included in the page limit. Pages must be numbered consecutively.

The project narrative may not exceed 25 pages of the 80 page limit. Applications that exceed the specified limits (total 10 MB or 80 pages when printed by HRSA) will be deemed non-compliant. All non-compliant applications will be returned to the applicant without further consideration.

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

SF 424 R&R – Table of Contents

It is mandatory to follow the instructions provided in this section to ensure that your application can be printed efficiently and consistently for review. Failure to follow the instructions may make your application non-compliant. Non-compliant applications will not be given any consideration and those particular applicants will be notified.

For electronic submissions, applicants only have to number the electronic attachment pages sequentially, resetting the numbering for each attachment, i.e., start at page 1 for each attachment. Do not attempt to number standard OMB approved form pages.
 For electronic submissions no table of contents is required for the entire application. HRSA will construct an electronic table of contents in the order specified.
 When providing any electronic attachment with several pages, add table of content page specific to the attachment. Such page will not be counted towards the page limit.

For paper submissions (when allowed), number each section sequentially, resetting the page number for each section. i.e., start at page 1 for each section. Do not attempt to number standard OMB approved form pages.
 For paper submissions ensure that the order of the forms and attachments is as specified below.
 Merge similar documents into a single document. Where several pages are expected in the attachment, ensure that you place a table of content cover page specific to the attachment. Table of content page will not be counted in the page limit.

Application Section	Form Type	Instruction	HRSA/Program Guidelines
SF 424R&R Cover Page	Form	Pages 1 & 2 of the R&R face page	Not counted in the page limit
Pre-application	Attachment	Can be uploaded on page 2 of SF 424 (R&R) - Box 20	Not Applicable to HRSA; Do not use.
HHS 5161 Checklist	Form	Also known as PHS 5161 checklist	Not counted in the page limit
SF 424R&R Senior/Key Person Profile	Form	Supports 8 structured profiles (PD + 7 additional)	Not counted in the page limit
Senior Key Personnel Biographical Sketches	Attachment	Can be uploaded in SF 424RR Senior/Key Person Profile form. One per each senior/key person. The PD/PI biographical sketch should be the first biographical sketch. Up to 8 allowed	Counted in the page limit.
Senior Key Personnel Current and Pending Support	Attachment	Can be uploaded in SF 424RR Senior/Key Person Profile form	Not Applicable to HRSA; Do not use.
Additional Senior/Key Person Profiles	Attachment	Can be uploaded in SF 424RR Senior/Key Person Profile form. Single document with all additional	Not counted in the page limit

Application Section	Form Type	Instruction	HRSA/Program Guidelines
		profiles	
Additional Senior Key Personnel Biographical Sketches	Attachment	Can be uploaded in the Senior/Key Person Profile form. Single document with all additional sketches	Counted in the page limit
Additional Senior Key Personnel Current and Pending Support	Attachment	Can be uploaded in the Senior/Key Person Profile form	Not Applicable to HRSA; Do not use.
SF 424RR Performance Site Locations	Form	Supports primary and 7 additional sites in structured form	Not counted in the page limit
Additional Performance Site Location(s)	Attachment	Can be uploaded in SF 424RR Performance Site Locations form. Single document with all additional site locations	Counted in the page limit
Project Summary/Abstract	Attachment	Can be uploaded in SF 424RR Other Project Information form, Box 6	Required attachment. Counted in the page limit. Refer guidance for detailed instructions. Provide table of contents specific to this document only as the first page
Project Narrative	Attachment	Can be uploaded in SF 424RR Other Project Information form, Box 7	Required attachment. Counted in the page limit. Refer guidance for detailed instructions. Provide table of contents specific to this document only as the first page
SF 424RR Budget Period (1-5) - Section A - B	Form	Supports structured budget for up to 5 periods	Not counted in the page limit
Additional Senior Key Persons	Attachment	SF 424RR Budget Period (1-5) - Section A - B, Box 9. One for each budget period	Not counted in the page limit
SF 424RR Budget Period (1-5) - Section C - E	Form	Supports structured budget for up to 5 periods	Not counted in the page limit
Additional Equipment	Attachment	SF 424RR Budget Period (1-5) - Section C - E, Box 11. One for each budget period	Not counted in the page limit
SF 424RR Budget Period (1-5) - Section F - J	Form	Supports structured budget for up to 5 periods	Not counted in the page limit
SF 424RR Cumulative Budget	Form	Total cumulative budget	Not counted in the page limit
Budget Narrative	Attachment	Can be uploaded in SF 424RR Budget Period (1-5) - Section F - J form, Box K. Only one consolidated budget justification for the project period.	Required attachment. Counted in the page limit. Refer guidance for detailed instructions. Provide table of contents

Application Section	Form Type	Instruction	HRSA/Program Guidelines
SF 424RR Subaward Budget	Form	Supports up to 10 budget attachments. This form only contains the attachment list	specific to this document only as the first page Not counted in the page limit
Subaward Budget Attachment 1-10	Attachment	Can be uploaded in SF 424RR Subaward Budget form, Box 1 through 10. Extract the form from the SF 424RR Subaward Budget PureEdge form and use it for each consortium/contractual/subaward budget as required by the program guidance. Supports up to 10	Filename should be the name of the organization and unique. Counted in the page limit
SF 424B Assurances for Non-Construction Programs	Form	Assurances for the SF 424 RR package	Not counted in the page limit
Other Project Information	Form	Allows additional information and attachments	Not counted in the page limit
Bibliography & References	Attachment	Can be uploaded in Other Project Information form, Box 8.	Required
Facilities & Other Resources	Attachment	Can be uploaded in Other Project Information form, Box 9.	Required
Equipment	Attachment	Can be uploaded in Other Project Information form, Box 10.	Required if appropriate for the project.
Other Attachments Form	Form	Supports up to 15 numbered attachments. This form only contains the attachment list	Not counted in the page limit
Attachment 1-15	Attachment	Can be uploaded in Other Attachments form 1-15	Refer to the attachment table provided below for specific sequence. Counted in the page limit
Other Attachments	Attachment	Can be uploaded in SF 424 RR Other Project Information form, Box 11. Supports multiple	Not Applicable to HRSA; Do not use

⚠ To ensure that attachments are organized and printed in a consistent manner, follow the order provided below. Note that these instructions may vary across programs.

⚠ Additional supporting documents, if applicable, can be provided using the available rows. Do not use the rows assigned to a specific purpose in the program guidance.

Attachment Number	Attachment Description (Program Guidelines)
Attachment 1	Staffing Plan, including personnel requirements and position descriptions
Attachment 2	Proof of nonprofit status for applicant organization
Attachment 3	Indirect Cost Rate Agreement
Attachment 4	Consortium agreements
Attachment 5	Letters of support
Attachment 6	Graphic/logic model illustrating proposed project and organizational chart
Attachment 7	Gantt or PERT chart
Attachment 8	Job descriptions for key personnel
Attachment 9	Other relevant documents

Note the following specific information related to your submission.

In addition to the SF 424 R&R forms, a complete application will include the following components in the order indicated on the SF 424 R&R *Other Project Information* form:

- Abstract
- Table of Contents
- Narrative
 - Introduction and Purpose
 - Needs Assessment
 - Methodology
 - Work Plan
 - Resolution of Challenges
 - Evaluation and Technical Support Capacity
 - Organizational Information
- Bibliography/List of References
- Facilities and Other Resources
- Equipment
- Attachments

Discussion and clarification of selected application components is provided below.

Application Format

i. Application Face Page

The SF 424 R&R, provided with the application package, includes a face page for general applicant and project information. Prepare this page according to instructions provided with the application package. For information pertaining to the Catalog of Federal Domestic Assistance (CFDA), the CFDA number is 93.134.

DUNS Number

All applicant organizations are required to have a Data Universal Numbering System (DUNS) number in order to apply for a grant from the Federal Government. The DUNS number is a unique nine-character identification number provided by the commercial company, Dun and Bradstreet. There is no charge to obtain a DUNS number. Information about obtaining a DUNS number can be found at <http://www.hrsa.gov/grants/dunscrr.htm> or by calling 866-705-5711. Include the DUNS number in Item 5 on application face page. Applications will not be reviewed without a DUNS number.

Additionally, the applicant organization is required to register with the Federal Government's Central Contractor Registry (CCR) in order to do electronic business with the Federal

Government. Information about registering with the CCR can be found at <http://www.hrsa.gov/grants/dunscsr.htm>.

ii. Table of Contents

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

iii. Application Checklist

Use the SF 424 R&R provided with the application package.

iv. Budget

Use the SF 424 R&R budget format provided with the application package.

Using the indicated budget sections of the SF 424 R&R, submit a consolidated budget (comprehensive budget including requested funding for all consortium organizations) for each year of the project period. Although the SF 424 R&R provides forms for five project years, the grant program under this funding announcement will not fund beyond three (3) years. The values on the cumulative budget forms will be calculated automatically in the electronic submission process.

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

Budget for Multi-Year Grant Award

This announcement is inviting applications for project periods up to three years. Awards, on a competitive basis, will be for a one-year budget period, although project periods may be for one to three years. Applications for continuation grants funded under these awards beyond the one-year budget period but within the multi-year project period will be entertained in subsequent years on a noncompetitive basis, subject to availability of funds, satisfactory progress of the grantee, and a determination that continued funding would be in the best interest of the Government.

v. Budget Justification

Provide a narrative that explains the amounts requested for each line in the budget. The budget justification should specifically describe how each item will support the achievement of proposed objectives. The budget period is for one year. A detailed budget justification is required from each organization for the first year of funding. The applicant also must submit

one-year budgets for each of the subsequent project period years (i.e., project year two and/or year three) at the time of application. Line item information must be provided to explain the costs entered in the budget forms of the SF 424 R&R. The budget justification must reflect the order of line items on these forms. Use the same structure for the budget justifications for all consortium organizations. The budget justification must clearly describe each cost element and explain how each cost contributes to meeting the project's objectives/goals. Development of intervention(s) may be supported by the grant but shall be limited to no more than 25 percent of project funding and staff time. Be informative about how items in the "other" categories are justified. The budget justification must be concise. Do not use the justification to expand the project narrative. Include the following in the Budget Justification narrative:

Include the following in the Budget Justification narrative:

Personnel Costs: Explain personnel costs by listing each staff member who will be supported from funds, name (if possible), position title, percent full time equivalency, annual salary, and the exact amount requested for each project year.

Indirect Costs: Indirect costs are costs incurred for common or joint objectives which cannot be readily identified but are necessary to the operations of the organization, e.g., the cost of operating and maintaining facilities, depreciation, and administrative salaries. For institutions subject to OMB Circular A-21, the term "facilities and administration" is used to denote indirect costs. If an organization applying for an assistance award does not have an indirect cost rate, the applicant may wish to obtain one through HHS's Division of Cost Allocation (DCA). Visit DCA's website at: <http://rates.psc.gov/> to learn more about rate agreements, the process for applying for them, and the regional offices which negotiate them. A copy of the latest negotiated cost agreement that covers the period for which funds are requested must be submitted in the appendix of the application.

Fringe Benefits: List the components that comprise the fringe benefit rate, for example health insurance, taxes, unemployment insurance, life insurance, retirement plan, tuition reimbursement. The fringe benefits must be directly proportional to that portion of personnel costs that are allocated for the project.

Travel: List travel costs according to local and long distance travel. Specify the mileage rate, number of miles, reason for travel and staff member/consumers completing the travel for local travel. The budget also should reflect the travel expenses associated with participating in meetings and other proposed trainings or workshops. These costs should include travel for two participants to attend a technical assistance (TA) workshop in the first year of the grant and one each year thereafter as explained in Section VIII B-C. Costs are for lodging, transportation, and per diem only and are based on travel costs to Washington, DC. In addition, two participants are required to attend one TA workshop per year in the second and third years of the grant. See *Section VIII. C., Technical Assistance Workshops*, for further requirements.

Equipment: List equipment costs and provide justification for the need of the equipment to carry out the program's goals. Extensive justification and a detailed status of current equipment must be provided if you are requesting funds for the purchase of computers and furniture items that meet the definition of equipment.

Supplies: List the items that the project will use. In this category, separate office supplies from medical and educational purchases by providing separate lists of office, medical, and educational supplies. Educational supplies must be justified as a reasonable, necessary, and integral part of a grant project. Also, an explanation of how the total numbers and costs of educational supplies were derived must be included.

Subcontracts: To the extent possible, all subcontract budgets and justifications should be standardized, and contract budgets should be presented by using the same object class categories contained in the Standard Form 424A. Provide a clear explanation as to the purpose of each contract, how the costs were estimated, and the specific contract deliverables. Categorize all contract costs according to type (e.g., translation services, transportation, childcare, consultants). If the contract is for a full time professional, provide justification for contracting instead of using an employee of the grantee institution. Treat payments to clients for performance of activities, such as client advocacy or peer education, the same as consultant payments only when they are working less than .5 FTE. Provide name of contractor, time spent working with the project, and rate of pay.

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

vi. Staffing Plan and Personnel Requirements

Applicants must present a staffing plan and provide a justification for the plan that includes education and experience qualifications and rationale for the amount of time being requested for each staff position. Position descriptions that include the roles, responsibilities, and qualifications of proposed project staff must be included as part of the SF 424 R&R submission process in the Senior/Key Person Profile section. Copies of biographical sketches for any key employed personnel that will be assigned to work on the proposed project must be included in the Senior Key Personnel Biographical Sketches attachment of the SF 424 R&R.

vii. Assurances and Certifications

The following assurances and certifications and other documentation required for award of funds in this grant program must be verified by the signature of the official/representative signing for the applicant organization on the face page of the application.

Assurances/certifications include: Human Subjects, Drug-Free Workplace, Lobbying, Non-Delinquency on Federal Debt, Research Misconduct, Civil Rights, Handicapped Individuals, Sex Discrimination, Age Discrimination, Financial Conflict of Interest, and Certification of Research Institution Participation.

Definitions are provided in Policies, Assurances, Definitions, and Other Information.

<ftp://ftp.hrsa.gov/grants/hhsgrantspolicystatement.pdf>. Compliance with these assurances and certifications is to be documented on page 2 of the SF 424 R&R face page provided with the application package.

viii. Project Abstract

Because the abstract is often distributed to provide information to the public and Congress, prepare the abstract so that it is clear, accurate, complete, concise, and without reference to other parts of the application. It must include a brief description of the proposed project including the needs to be addressed, the proposed intervention, and the population group(s) to be served. The abstract will be utilized extensively in the review process. It is essential, therefore, that the abstract reflect the most critical points of the application.

The project abstract must be single-spaced and limited to one (1) page in length. Abstract pages beyond one page will be discarded. In describing the research design and methods within the abstract, the proposed data collection methods must be included.

Place the following at the top of the abstract:

- Project Title
- Applicant Name
- Principle Investigator
- Address
- Contact Phone Numbers (Voice, Fax)
- E-Mail Address
- Web Site Address
- Consortium Member Names

ix. Project Narrative

This section of the application provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, complete, and well organized so that reviewers can understand the proposed project. The project narrative should include sufficient information to enable the evaluation of the project. Be specific and informative and avoid redundancies. The following subsections should not exceed 25 pages.

Use the following section headers for the Project Narrative and include these section headers in the Table of Contents:

▪ *INTRODUCTION AND PURPOSE*

Briefly describe the purpose of the proposed project and the anticipated accomplishments (goals), including knowledge gained, and describe the measurable steps (objectives) to achieve the accomplishments. State clearly why the specific interventions proposed are expected to have a substantial positive impact on improving UDCD practices.

▪ *NEEDS ASSESSMENT*

This section outlines the need for and potential significance of the project in a specific community or population. Include relevant published and unpublished data and observational information with appropriate citations to support the need for and potential significance of the project. While data briefly illustrating national need may provide context, discussion of local need or assessment of need specific to the target population should be included. Describe the purpose and usefulness of demographic data and discuss relevant barriers that the project aims to overcome. This section is intended to

help reviewers understand the community and/or organization that will be served by this activity. If this is a replication study or an outgrowth of a previous project, the original study must be discussed. Include the previous study's purpose, funding source, findings, and the rationale for replication. Include a comprehensive review of studies, knowledge, and/or practices relevant to the proposed topic, referencing relevant studies from the broader health education and public health literature.

▪ **METHODOLOGY**

Discuss proposed methods that will be used to meet each of the previously described program requirements and expectations in this grant program guidance. Discuss the utility of proposed research approaches, paying particular attention to new approaches, if employed. Document whether the proposed methodology has been successfully used previously. If it is a new approach, describe its appropriateness for the proposed project. The methodology section also should provide a complete description of the following elements:

Intervention -

[a] a detailed description of the intervention;

[b] the intervention's potential for increasing procurement;

[c] an explanation of the clinical principals/foundations upon which the intervention is based;

[d] where multi-pronged interventions are being used, a thorough description of each;

[e] a review of relevant descriptive information and data relating to feasibility and effectiveness from work using the same or similar interventions, including recommended refinements/modifications; and

[f] the potential of the intervention to be effectively replicated, transferred, and applied by institutions/organizations with similar competencies and target populations.

Target Population –

[a] justification for the target population; description of the size and characteristics of the target population;

[b] rationale for selecting the specific geographic area for project implementation and its appropriateness for reaching the identified target population;

[c] indication that the project team has the experience and expertise necessary to understand, reach, and influence the target population; and

[d] plans for recruitment and retention of the target group.

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

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

Outcome Measures and Evaluation Plan –

[a] a thorough description of, and rationale for, the proposed research methods including: a discussion of how the proposed evaluation can be expected to produce reliable data on intervention outcomes and effectiveness;

[b] proposed performance measures upon which the project will be evaluated, which must include at least one of the following measures: organ procurement, or number of transplantable organs;

[c] sampling methods, number of subjects, sample size and power calculations;

[d] measurement tools, data collection, transfer and reduction; and

[f] relevance/appropriateness of the data elements to producing a verifiable and demonstratable impact on procurement.

Instruments – descriptions, and if possible data collection instruments, e.g. data collection forms, patient record forms, protocol forms, case report forms etc...

▪ ***WORK PLAN***

Describe the activities or steps that will be used to achieve each of the activities proposed in the methodology section. Use a timeline that includes each activity and identifies responsible staff for all phases and years of the proposed project, including a proposal for dissemination of project outcomes. This timeline will contribute to the assessment of each year's progress. A graphic representation (Gantt PERT chart) attached as an appendix is helpful in the review process.

▪ ***RESOLUTION OF CHALLENGES***

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

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

Discuss relevant experience, skills, and knowledge of key project staff to conduct this project, including materials published and previous work of a similar nature. It is not necessary to repeat all information included in biosketches, but rather to justify qualifications and appropriateness for the project role.

▪ ***ORGANIZATIONAL INFORMATION***

Discuss adequacy of the collective resources (the applicant agency, consortium member organizations, and key staff) for conducting the proposed project. For all key organizations, briefly indicate current mission and structure, scope of current activities, and how these contribute to the ability of the project team to conduct the program requirements and meet program expectations. In order to conserve space, it is recommended that applicants provide this information in the project narrative in approximately one paragraph per consortium member.

x. ***Attachments***

Provide the following items to complete the content of the application. The attachments are supplementary in nature and should not be used as an extension of the narrative. You will include them as attachments during the application process. Be sure each attachment is clearly labeled and placed in the correct attachment section of the electronic application. Applicants are reminded that Senior/Key Person Profile Forms and biographical sketches are submitted as sections of the SF 424 R&R. Attachments include but are not limited to the following:

- Attachment 1– Staffing plan, personnel requirements, position descriptions (required) – applicants must present a staffing plan and justification for the plan that includes

rationale for the amount of time being requested for each project component. Position descriptions that include the roles, responsibilities, and qualifications for proposed project positions must be included.

- Attachment 2 – Proof of nonprofit or public status for applicant organization (required)
- Attachment 3 – Indirect Cost Rate Agreement (required for organizations that have Federally approved Indirect Cost Rate Agreement)
- Attachment 4 – Consortium agreements (required) – signed and dated letter or memorandum of understanding from each consortium member indicating its commitment and specific project role(s) and responsibilities
- Attachment 5 – Letters of support (required) – documentation from organizations and individuals who are not consortium members but have important roles in the project, e.g., implementation or control sites, associated community organizations. Form letters or letters indicating only vague support generally are not useful. Include only letters of support that specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.). Letters of support must be dated. List all other support letters on one page.
- Attachment 6 – Graphic/logic model illustrating proposed project and project organizational chart (encouraged, not required); include subcontractors and other significant collaborators
- Attachment 7 – Gantt or PERT chart outlining work plan (encouraged, not required)
- Attachment 8 – Job descriptions for key personnel (required); keep each to one page in length
- Attachment 9 – Other relevant documents (optional)

3. Submission Dates and Times

Notification of Intent to Apply:

An applicant is eligible to apply even if no letter of intent is submitted. Receipt of letters of intent will *not be acknowledged*. This letter should identify the applicant organization and key consortium organizations and should briefly describe the project to be submitted.

This letter should be sent by April 23, 2007, by mail or fax to:

Division of Independent Review
Director
HRSA Grants Application Center (GAC)
Announcement No. HRSA-07-077
The Legin Group, Inc.
910 Clopper Road, Suite 155 South
Gaithersburg, MD 20878
Fax: 877-477-2345

Application Due Date

The due date for applications under this grant announcement is May 10, 2007 at 8:00 P.M. Eastern Time (ET). Applications will be considered as meeting the deadline if they are E-

marked on or before the due date. Please consult guidance Appendix A (*HRSA's Electronic Submission User Guide*), Section 3 for detailed instructions on submission requirements.

The Chief Grants Management Officer or a higher level designee may authorize an extension of published deadlines when justified by circumstances such as acts of God (e.g., floods or hurricanes), widespread disruptions of mail service, or other disruptions of services, such as a prolonged blackout. The authorizing official will determine the affected geographical area(s).

Applications must be submitted by 8:00 P.M. ET. **To ensure that you have adequate time to follow procedures and successfully submit the application, it is recommended that you register immediately in Grants.gov (see Appendix B) and complete the forms as soon as possible, as this is a new process and may take some time.**

Please refer to this guidance's Appendix B (*Registering and Applying through Grants.gov*) for important specific information on registering, and Appendix A (*HRSA's Electronic Submission User Guide*), Section 3 for important information on applying through Grants.gov.

Late applications:

Applications that do not meet the criteria above are considered late applications. The Health Resources and Services Administration (HRSA) shall notify each late applicant that its application will not be considered in the current competition.

4. Intergovernmental Review

Executive Order (EO) 12372:

The Clinical Interventions Grant Program is a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. Application packages made available under this announcement will contain a listing of States that have chosen to set up such a review system, and will provide a State Single Point of Contact (SPOC) for the review. Information on states affected by this program and State Points of Contact also may be obtained from the Grants Management Officer listed under Agency Contacts, *Section VII* of this guidance, as well as from the following Web site: <http://www.whitehouse.gov/omb/grants/spoc.html>.

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

Letters from the State Single Point of Contact (SPOC) in response to Executive Order 12372 are due sixty days after the application due date.

5. Funding Restrictions

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

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

- Funds may not be used to supplant or replace current public or private research funding.
- Funds may not be used to purchase or improve land, or to purchase, construct, or make permanent improvements to any building except for minor remodeling.
- Funds may not be used to make payments to recipients of services, except for reimbursement of reasonable and allowable out-of-pocket expenses associated with participation in project activities.
- Funds may not be used to support: (a) brain death donation; (b) living donation; (c) research using animals; (d) interventions to increase tissue donation alone; (e) practices related to the pronouncement of death; (f) interventions inconsistent with existing Federal law.
- Funded staff time devoted to project activities must not receive additional reimbursement from other sources.
- Funds may not be used to reimburse pre-award costs.
- Unobligated funds at the end of the budget period are restricted and remain in the grant account for future HRSA disposition. These funds may be requested for carryover to the next budget period. Unobligated funds are those reported on the annual Financial Status Report (SF-269), which is required to be submitted to HRSA within 90 days after the end of the budget period for each project year.

Allowable administrative functions/costs include:

- a) usual and recognized overhead, including indirect rates for all consortium members that have a Federally approved indirect cost rate; and
- b) management and oversight of specific project components funded under the grant program.

6. Other Submission Requirements

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

As soon as you read this, whether you plan on applying for a HRSA grant later this month or later this year, it is incumbent that your organization **immediately register** in Grants.gov and

become familiar with the Grants.gov site application process. If you do not complete the registration process you will be unable to submit an application. The registration process can take up to one month, so you need to begin immediately.

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

- Obtain an organizational Data Universal Number System (DUNS) number
- Register the organization with Central Contractor Registry (CCR)
- Identify the organization's E-Business POC (Point of Contact)
- Confirm the organization's CCR "Marketing Partner ID Number (M-PIN)" password
- Register an Authorized Organization Representative (AOR)
- Obtain a username and password from the Grants.gov Credential Provider

Instructions on how to register, tutorials and FAQs are available on the Grants.gov web site at www.grants.gov. Assistance also is available from the NIH Grants.gov help desk at support@grants.gov or by phone at 1-800-518-4726. Although the help desk telephone answering system says it is responding to questions about NIH grants, it also is available to assist HRSA grant applicants.

More specific information, including step-by-step instructions on registering and applying, can be found in the Appendix B (*Registering and Applying Through Grants.gov*) of this guidance.

Formal submission of the electronic application: Applications completed online are considered formally submitted when the Authorizing Official electronically submits the application to HRSA. However, to complete the submission requirements, a hard-copy of the SF 424 R&R Face Sheet must be printed, signed, and submitted to the HRSA Grants Application Center. The SF 424 R&R Face Page must be printed from Grants.gov.

For an online application, the signed SF 424 R&R Face Page must be sent to the HRSA Grants Application Center at the following address and received by HRSA by no later than five (5) days after the date of submission in Grants.gov.

The HRSA Grants Application Center
The Legin Group, Inc.
Attn: Clinical Interventions to Increase Organ Procurement Grant Program
Program Announcement No. HRSA-07-077
CFDA No. 93.134
910 Clopper Road, Suite 155 South
Gaithersburg, MD 20878
Telephone: 877-477-2123

Applications will be considered as having met the deadline if: (1) the application has been successfully transmitted electronically by the applicant organization's Authorizing Official through Grants.Gov on or before the deadline date and time, and (2) the signed SF 424 R&R Face Page is received by HRSA no later than five (5) days after the date of submission in Grants.gov.

It is incumbent on applicants to ensure that the Authorized Official is available to submit the application to HRSA by the application due date. We will not accept submission or re-submission of incomplete, rejected, or otherwise delayed applications after the deadline.

Again, please understand that we will not consider additional information and/or materials submitted after your initial application. You must therefore ensure that all materials are submitted together.

V. Application Review Information

Procedures for assessing the technical merit of grant applications have been instituted to provide for an objective review of applications and to assist the applicant in understanding the standards against which each application will be judged. Critical indicators have been developed for each review criterion to assist the applicant in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. Review criteria, according to which all applications will be evaluated, are outlined below with specific detail and scoring points. Applications will be evaluated by a peer review committee. Applicants should pay strict attention to addressing all these criteria, as they are the basis upon which the reviewers will evaluate their applications.

1. Review Criteria

Review Criteria are used to review and rank applications. The Clinical Interventions to Increase Organ Procurement Grant Program has six (6) review criteria:

(1) Need – (20 Points)

The extent to which the application describes the problem and associated contributing factors to the problem and the overall impact that the intervention has (with or without refinement) of succeeding.

(2) Response – (20 Points)

The extent to which the proposed project responds to the “Purpose” included in the program description. The clarity of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives.

(3) Evaluative Measures –(20 Points)

The degree of scientific rigor in the design, implementation and evaluation of the project. Specifically the effectiveness of the methods proposed to monitor and evaluate the project results. Evaluative measures must be able to assess 1) to what extent the program objectives have been met and 2) and to what extent they can be attributed to the project

(4) Impact –(20 Points)

The extent and effectiveness of plans for dissemination of project results and/or the extent to which project results may be replicable, transferable, practical and sustainable beyond Federal funding.

- a. Replicability – effectiveness of the intervention in repeated evaluations
- b. Transferability – likelihood that the intervention can be implemented by organizations with similar competencies
- c. Practicality – feasibility of implementing the intervention on a broader scale in terms of required human, financial and other resources. Evidence demonstrating the potential benefits (e.g. the likely increase in organs procured and transplanted) relative to project costs will also be considered.

(5) Resource Capabilities –(10 Points)

The extent to which project personnel are qualified by training and/or experience to implement and carry out the project. The capability of the applicant organization(s), including the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project.

(6) Support Requested – (10 Points)

The reasonableness of the proposed budget in relation to the objectives, the complexity of the activities, and the anticipated results.

2. Review and Selection Process

The Division of Independent Review is responsible for managing objective reviews within HRSA. Applications competing for federal funds receive an objective and independent review performed by a committee of experts qualified by training and experience in particular fields or disciplines related to the program being reviewed. In selecting review committee members, other factors in addition to training and experience may be considered to improve the balance of the committee, e.g., geographic distribution. Each reviewer is screened to avoid conflicts of interest and is responsible for providing an objective, unbiased evaluation based on the review criteria noted above. The committee provides expert advice on the merits of each application to program officials responsible for final selections for award.

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

VI. Award Administration Information

1. Award Notices

Each applicant will receive written notification of the outcome of the objective review process, including a summary of the committee’s assessment of the application’s merits and weaknesses, and whether the application was selected for funding. Applicants who are selected for funding may be required to respond in a satisfactory manner to conditions placed

on their application before funding can proceed. Letters of notification do not provide authorization to begin performance.

The Notice of Grant Award (NGA) sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided (if applicable), and the total project period for which support is contemplated. Signed by the Grants Management Officer, it is sent to the applicant agency's Authorized Representative, and reflects the only authorizing document. It will be sent prior to the start date of September 1, 2007.

2. Administrative and National Policy Requirements

Successful applicants must comply with the administrative requirements outlined in 45 CFR Part 74 (http://www.access.gpo.gov/nara/cfr/waisidx_05/45cfr74_05.html, for institutions and other organizations) or 45 CFR Part 92 (http://www.access.gpo.gov/nara/cfr/waisidx_05/45cfr92_05.html, for state, local, and tribal governments), as appropriate.

Beginning October 1, 2006, HRSA grant awards will be subject to the requirements of the HHS Grants Policy Statement (HHS GPS) that are applicable to the grant based on recipient type and purpose of award. This includes, as applicable, any requirements in Parts I and II of the HHS GPS that apply to the award, as well as any requirements of Part IV. The HHS GPS is available at <http://www.hrsa.gov/grants/>. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in the Notice of Award).

PUBLIC POLICY ISSUANCE

Healthy People 2010

Healthy People 2010 is a national initiative led by HHS that sets priorities for all HRSA programs. The initiative has two major goals: (1) to increase the quality and years of a healthy life; and (2) to eliminate our country's health disparities. The program consists of 28 focus areas and 467 objectives. HRSA has actively participated in the work groups of all the focus areas, and is committed to the achievement of the *Healthy People 2010* goals.

Applicants must summarize the relationship of their projects and identify which of their programs objectives and/or sub-objectives relate to the goals of the *Healthy People 2010* initiative.

Copies of the *Healthy People 2010* may be obtained from the Superintendent of Documents or downloaded from the *Healthy People 2010* website:
<http://www.health.gov/healthypeople/document/>.

Smoke-Free Workplace

The Public Health Service strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. Further, Public Law 103-227,

the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children.

Human Subjects

In order to assure compliance with the Code of Federal Regulations (CFR), Title 45 – Public Welfare, Part 46 – Protection of Human Subjects, which can be found on the Internet at www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm, grantees must complete two actions prior to any collection of data:

- (1) Secure a Federal-Wide Assurance for all organizations participating in the project from the HHS Office of Human Research Protections (OHRP). Information on obtaining Assurances can be found on the Internet at www.hhs.gov/ohrp/assurances/assurances_index.html or by emailing inquiries to ohrp@osophs.dhhs.gov.
- (2) Obtain approval from an Institutional Review Board (IRB) registered with the HHS' OHRP. While completed IRB review is not required prior to submission of the grant application, applicants must indicate the organization that will conduct the review. A list of independent IRBs is available by visiting the OHRP Web site listed above. Applications must provide a detailed description of expected requirements and actions for protection of human subjects within the methodology section of the application. If funded, grantees must obtain human subjects clearance before each year of their project. Exemption is granted only by an IRB and cannot be determined by the applicant without submission to an IRB.

3. Reporting

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

a) Audit Requirements

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

b) Payment Management Requirements

That each grantee submit a quarterly electronic PSC-272 via the Payment Management System. The report identifies cash expenditures against the authorized funds for the grant. Failure to submit the report may result in the inability to access grant funds. The PSC-272 Certification page should be faxed to the PMS contact at the fax number listed on the 272 form, or it may be submitted to the:

Division of Payment Management
HHS/ASAM/PSC/FMS/DPM
PO Box 6021
Rockville, MD 20852
Telephone: (877) 624-5533;

c) Status Reports

1. Submit a **Financial Status Report**. A financial status report is required within 90 days of the end of each grant year. The report is an accounting of expenditures by the project that year. More Specific information will be included in the award notice;
2. Submit a **Progress Report(s)**. Progress reports due by the 15th of each December, April, and July. Progress reports should be submitted electronically.
3. Submit other required reports. Submit an annual noncompeting continuation application that will also serve as the year-end progress report. Grantees will receive a Noncompeting Continuation Guidance to assist in the preparation of this application, which is to be submitted electronically.

d) Performance Review

HRSA's Office of Performance Review (OPR) serves as the agency's focal point for reviewing and enhancing the performance of HRSA-funded programs within communities and States. As part of this agency-wide effort, HRSA grantees will be required, where appropriate, to participate in an on-site performance review of their HRSA funded program(s) by a review team from one of the ten OPR regional divisions. Grantees should expect to participate in a performance review at some point during their project period. When a grantee receives more than one HRSA grant, each of the grantee's HRSA funded programs will be reviewed during the same performance review.

The purpose of performance review is to improve the performance of HRSA-funded programs. Through systematic pre-site and on-site analysis, OPR works collaboratively with grantees and HRSA Bureaus/Offices to measure program performance, analyze the factors impacting performance, and identify effective strategies and partnerships to improve program performance, with a particular focus on outcomes. Upon completion of the performance review, grantees will be required to prepare an action plan that identifies key actions to improve program performance as well as addresses any identified program requirement issues. In addition, performance reviews also provide an opportunity for grantees to offer direct feedback to the agency about the impact of HRSA policies on program implementation and performance within communities and States.

For additional information on performance reviews, please visit:
<http://www.hrsa.gov/performance-review>.

VII. Agency Contacts

Applicants may obtain additional information and assistance regarding government forms, business, administrative, or fiscal issues related to this grant announcement by contacting:

Jacqueline Whitaker
Lead Grants Management Specialist
Research and Training Branch

Division of Grants Management Operations
Office of Financial Assistance Management, HRSA
5600 Fishers Lane, Room 11A-16
Rockville, MD 20857
Telephone: 301-443-3893
Fax: 301-443-6343
E-Mail: jwhitaker@hrsa.gov

Applicants may obtain technical assistance regarding this guidance and additional information related to overall program issues by contacting:

Jade K. Perdue, M.P.A.
Public Health Analyst
Operations and Analysis Branch, Division of Transplantation
Healthcare Systems Bureau, HRSA
5600 Fishers Lane, Room 12C-06
Rockville, MD 20857
Telephone: 301-443-3124
Fax: 301-594-6095
E-Mail: jperdue@hrsa.gov

VIII. Other Information

A. Internet Resources

Applicants are encouraged to refer to DoT's web site, www.organdonor.gov, for general information about government donation initiatives and transplantation issues.

B. Pre-Application Workshop

DoT is planning to hold at least one technical assistance workshop and/or conference call in early 2007 for potential applicants in this funding opportunity. When details are available, information will be posted on www.organdonor.gov. Further information may be obtained by contacting Ms. Jade Perdue at jperdue@hrsa.gov or 301-443-3124.

C. Technical Assistance Workshops/Conference Calls

In order to ensure coordination/collaboration among grantees, maximize effectiveness and efficiency, and allow flexibility in the face of rapid changes in the field, all funded projects are required to participate one-two (1-2) Grantee Technical Assistance (TA) Workshops and/or conference call during the first project year, one of which will be pre-implementation, and one (1) workshop/conference call or more as required by the project officer during each subsequent year of project funding. The researcher/evaluator and key donation or transplantation professional from each funded project are required to participate. While there is no cost for the workshops themselves, applicants should include in the budget section funding for lodging, transportation, and per diem for two participants. Grant funds may be used to support workshop attendance for only two individuals. Conference calls will be provided by DoT and all

researchers are encouraged to participate. Applicants should use Washington, DC to estimate their expenses, although workshops may be held elsewhere.

The purpose of the Technical Assistance Workshops and/or conference call(s) will be to discuss the critical components of each project, assess progress, identify problem areas and potential solutions, develop strategies for achieving maximum efficacy of each project, and promote networking among grantees with like interests. Workshop consultants will review projects and provide suggestions to grantees on issues such as project intervention, design, approach, outcome measures, budget, and parameters. They will assess the use of qualitative measurements and suggest modifications/refinements to ensure continued feasibility and usefulness. Suggested budget revisions commensurate with project revisions must be submitted to the Federal Government for review and approval.

D. Final Presentation

At project completion, each grantee may be asked to conduct a final presentation up to one hour in duration for DoT staff and other HRSA/HHS representatives. Information shall include: description of the intervention and approach, findings, conclusions, challenges and solutions experienced, and contributions of the project in terms of impact on donation. Grant funds may be used for up to two project representatives to travel to conduct the final presentation. Presenters should be prepared to address questions about the implementation, outcomes, and evaluation of the project. Washington, D.C can be used to estimate travel costs.

E. Data Coordination and Management

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

F. Publication and Presentation of Project Findings

Publication of major findings is encouraged. *All* publications and oral presentations of work performed under, and data resulting from, this grant must contain appropriate acknowledgment of HRSA support and a disclaimer as follows: "This publication/presentation was supported by Grant No. ____ from the Health Resources and Services Administration's Division of Transplantation (HRSA/DoT), U.S. Department of Health and Human Services. The contents of this publication/presentation are solely the responsibility of the author(s) and do not necessarily represent the views of HRSA/DoT." In addition, HRSA must be notified in advance of all publications and presentations to enable coordination of announcements about the oral or written presentation of information resulting from the project funded under this grant program.

IX. Tips for Writing a Strong Application

Include DUNS Number. You must include a DUNS Number to have your application reviewed. Applications *will not* be reviewed without a DUNS number. To obtain a DUNS number, access www.dunandbradstreet.com or call 866-705-5711. Include the DUNS number in Item 5 of the application face page.

Keep your audience in mind. Reviewers will use only the information contained in the application to assess the application. Be sure the application and responses to the program requirements and expectations are complete and clearly written. Do not assume that reviewers are familiar with the applicant organization. Keep the review criteria in mind when writing the application.

Start preparing the application early. Allow plenty of time to gather required information from various sources.

Follow the instructions in this guidance carefully. Failure to do so may result in a loss of points or non-review of application.

Be complete, concise, and clear. Make your points understandable. Provide sufficient but not superfluous discussion. Provide accurate and honest information, including candid accounts of potential difficulties and realistic plans to address them. If any required information or data is omitted, explain why. Make sure the information provided in each table, chart, attachment, etc., is consistent with the proposal narrative and information in other tables.

Consider page limitations when compiling application – conserve where possible. Carefully selecting a small number of consortium organizations will help with the number of budget and budget justification pages. Biosketches for key personnel can be limited to two pages each. Avoid redundancies. In literature reviews, cite only the relevant findings and provide references for further information. Provide only information about capacity to undertake project, not organizational marketing. Limit Consortium Agreements and letters of support to one page each.

Be organized and logical. Many applications fail to receive high scores because the issues and concepts are not coherently linked or because parts of the application do not fit together.

Incorporate attachments appropriately. Do not use the attachments for information that is required in the body of the application. Be sure to cross-reference all tables and attachments to the appropriate text in the application.

Carefully proofread the application. Misspellings and grammatical errors will detract from an application's overall presentation. Limit the use of abbreviations and acronyms, and define each one at its first use and periodically throughout application. Adhere to stated page limits. Make sure you submit your application in final form, without markups.

Print out and carefully review the electronic application. Print out the application before submitting it to ensure appropriate formatting and adherence to page limit requirements.

Check to ensure that all attachments are included in your electronic submission before sending the application forward.

Ensure that all information is submitted at the same time. We will not consider additional information and/or materials submitted after your initial submission, nor will we accept e-mailed applications or supplemental materials once your application has been accepted.

APPENDIX A: HRSA’s Electronic Submission User Guide

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1. Introduction

1.1 Document Purpose and Scope

Major changes are coming to HRSA's Grant Application Process. For guidances released/posted on or after January 1, 2006, HRSA will no longer accept applications for grant opportunities on paper. Applicants submitting new and competing continuations and a selected number of noncompeting continuation applications will be required to submit electronically through Grants.gov. All applicants must submit in this manner unless the applicant is granted a written exemption from this requirement in advance by the Director of HRSA's Division of Grants Policy.

The purpose of this document is to provide detailed instructions to help applicants and grantees submit applications electronically to HRSA through Grants.gov. The document is intended to be the comprehensive source of all information related to the new processes that HRSA and its customers have to adopt and will be updated periodically. This document is not meant to replace program guidance documents for funding announcements.

1.2 Document Organization and Version Control

This document contains 5 sections apart from the Introduction. Following is the summary:

Section	Description
Noncompeting Continuation Application	Provides detailed instructions to existing HRSA grantees for applying electronically using Grants.gov for all noncompeting announcements
Competing Application	Provides detailed instructions to applicant organizations for applying electronically using Grants.gov for all competing announcements
General Instructions for Application Submission	Provides instructions and important policy guidance on application format requirements
Customer Support Information	Provides contact information to address technical and programmatic questions
Frequently Asked Questions (FAQs)	Provides answers to frequently asked questions by various categories

This document is under version control. Please visit <http://www.hrsa.gov/grants> to retrieve the latest published version.

2. Noncompeting Continuation Application

2.1 Process Overview

Following is the process for submitting a noncompeting continuation application through Grants.gov:

1. HRSA will communicate noncompeting announcement number to the project director (PD) and authorizing official (AO) via email. The announcement number will be required to search for the announcement in Grants.gov.
2. Search for the announcement in Grants.gov Apply (<http://www.grants.gov/Apply>).
3. Download the application package and instructions from Grants.gov. The program guidance is also part of the instructions that must be downloaded.
4. Save a local copy of the application package on your computer and complete all the forms based on the instructions provided in the program guidance.
5. Submit the application package through Grants.gov. (Requires registration)

6. Track the status of your submitted application at Grants.gov until you receive a notification from Grants.gov that your application has been received by HRSA.
7. HRSA Electronic Handbooks (EHBs) software pulls the application information into EHBs and validates the data against HRSA's business rules.
8. HRSA notifies the project director, authorizing official, business official (BO) and application point of contact (POC) by email to check HRSA EHBs for results of HRSA validations and enter additional information, including in some cases performance measures, necessary to process the noncompeting continuation.
9. AO verifies the application in HRSA EHBs, fixes any validation errors, makes necessary corrections and submits the application to HRSA. (Requires registration)
10. AO prints the application face page from HRSA EHBs (not Grants.gov), signs it and mails it to HRSA's Grant Application Center (GAC).
11. HRSA receives the signed face page and scans it into the system saving it with the electronic application.

2.2 Grantee Organization Needs to Register with Grants.gov (if not already registered) – See Appendix B

Grants.gov requires a **one-time** registration by the applicant organization. This is a three step process and should be completed by any organization wishing to apply for grant. If you do not complete this registration process you will not be able to submit an application. The registration process will require some time (anywhere from 5 business days to a month). Therefore, applicants or those considering applying at some point in the future should register immediately. Registration with Grants.gov provides the individuals from the organization the required credentials in order to apply.

If an applicant organization has already completed Grants.gov registration for another Federal agency, this section can be skipped.

For those applicant organizations still needing to register with Grants.gov, registration information can be found on the Grants.gov Get Started website (<http://www.grants.gov/GetStarted>). To be able to successfully register in Grants.gov, it is necessary that you complete all of the following required actions:

- Obtain an organizational Data Universal Number System (DUNS) number
- Register the organization with Central Contractor Registry (CCR)
- Identify the organization's E-Business POC (Point of Contact)
- Confirm the organization's CCR "Marketing Partner ID Number (M-PIN)" password
- Register an Authorized Organization Representative (AOR)
 - Obtain a username and password from the Grants.gov Credential Provider
 - Register the username and password with Grants.gov
 - Get authorized as an AOR by your organization

In addition, if an applicant does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. Beginning Oct. 30, 2005, the CCR also validates the EIN against Internal Revenue Service records, a step that will take one to two business days.

Please direct questions regarding Grants.gov registration to the Grants.gov Contact Center at Tel.: 1-800-518-4726. Contact Center hours of operation are Monday-Friday from 7:00 a.m. to 9:00 p.m. Eastern Time, excluding Federal holidays.

 **It is recommended that this registration process be completed at least two weeks prior to the submittal date of your organization's first Grants.gov submission.**

2.3 Project Director and Authorizing Official Need to Register with HRSA EHBs (if not already registered)

In order to access your noncompeting continuation application in HRSA EHBs, existing grantee organizations must register within the EHBs. The purpose of the registration process is to collect consistent information from all users, avoid collection of redundant information and allow for the unique identification of each system user. Note that registration within HRSA EHBs is required only **once for each user for each organization they represent**.

Registration within HRSA EHBs is a two-step process. In the first step, individual users from an organization who participate in the grants process such as applying for noncompeting continuations must create **individual** system accounts. In the second step, the users must associate themselves with the appropriate grantee organization. **To find your organization record use the 10-digit grant number from the Notice of Grant Award (NGA) belonging to your grant.** Note that since all existing grantee organization records already exist within EHBs, there is no need to create a new one.

To complete the registration quickly and efficiently we recommend that you have the following information handy:

1. Identify your role in the grants management process. HRSA EHBs offer the following three functional roles for individuals from applicant/grantee organizations:
 - Authorizing Official (AO),
 - Business Official (BO), and
 - Other Employee (for project directors, assistant staff, AO designees and others).For more information on functional responsibilities refer to the HRSA EHBs online help.
2. 10-digit grant number from the latest NGA belonging to your grant (Box 4b on NGA). You must use the grant number to find your organization during registration. All individuals from the organization working on the grant must use the same grant number to ensure correct registration.


In order to access the noncompeting application, the project director and other participants have to register the specific grant and add it to their respective portfolios. This step is required to ensure that only the authorized individuals from the organization have access to grant data. **Project directors will need the last released NGA in order to complete this additional step.** Again, note that this is a one time requirement.

The project director must give the necessary privileges to the authorizing official and other individuals who will assist in the noncompeting continuation application submission using the administer feature in the grant handbook. The project director should also delegate the “Administer Grant Users” privilege to the authorizing official.

Once you have access to your grant handbook, use the “Noncompeting Continuations” link under the deliverables section to access your noncompeting application.

Note that registration with HRSA EHBs is independent of Grants.gov registration.

For assistance in registering with HRSA EHBs, call 877-GO4-HRSA (877-464-4772) between 9:00 am to 5:30 pm ET or email callcenter@hrsa.gov.


 **You must use your 10-digit grant number (box 4b from NGA) to identify your organization.**

2.4 Apply through Grants.gov

2.4.1 Find Funding Opportunity

Search for the announcement in Grants.gov **Apply** (<http://www.grants.gov/Apply>).

Enter the announcement number communicated to you in the field *Funding Opportunity Number*. (Example announcement number: 5-S45-06-001)

 **Noncompeting announcements are not available in Grants.gov FIND!**


2.4.2 Download Application Package

Download the application package and instructions. In order to view application package and instructions, you will also need to download and install the PureEdge Viewer (<http://www.grants.gov/DownloadViewer>). This small, free program will allow you to access, complete, and submit applications electronically and securely.

 **Please review the system requirements for PureEdge Viewer on the Grants.gov website.**


2.4.3 Complete Application

Complete the application using both the built-in instructions and the instructions provided in the program guidance. Ensure that you save a copy of the application on your local computer.

 **Ensure that you provide your 10-digit grant number (box 4b from NGA) in the Federal Award Identifier field (box 5b in SF424 or box 4 in SF424 R&R)**

Please direct questions regarding PureEdge to Grants.gov. Contact the Grants.gov Contact Center at Tel.: 1-800-518-4726. Contact Center hours of operation are Monday-Friday from 7:00 a.m. to 9:00 p.m. Eastern Time, excluding Federal holidays.

For assistance with program guidance related questions, please contact the program contact listed on the program guidance.


 **You can complete the application offline – you do not have to be connected to the Internet.**

2.4.4 Submit Application

The "Submit" button on the application package cover page will become active after you have downloaded the application package, completed all required forms, attached all required documents, and saved your application package. Click on the "Submit" button once you have done all these things and you are ready to send your completed application to Grants.gov.

Review the provided application summary to confirm that the application will be submitted to the program you wish to apply for. To submit, you will be asked to Log into Grants.gov. Once you have logged in, your application package will automatically be uploaded to Grants.gov. A confirmation screen will appear once the upload is complete. Note that a Grants.gov Tracking number will be provided on this screen. Please record this number so that you may refer to it for all subsequent help.

Please direct questions regarding application submission to the Grants.gov Contact Center at Tel.: 1-800-518-4726. Contact Center hours of operation are Monday-Friday from 7:00 a.m. to 9:00 p.m. Eastern Time, excluding Federal holidays.

 **You must be connected to the Internet and must have a Grants.gov username and password to submit the application package.**


2.4.5 Verify Status of Application

Once Grants.gov has received your submission, Grants.gov will send email messages to advise you of the progress of your application through the system. Over the next 24 to 48 hours, you should receive two emails. The first will confirm receipt of your application by the Grants.gov system ("Received"), and the second will indicate that the application has either been successfully validated ("Validated") by the system prior to transmission to the grantor agency or has been rejected due to errors ("Rejected with Errors").

In case of any errors, you must correct the application and resubmit it to Grants.gov. If you are unable to resubmit because the opportunity has since closed, **contact the HRSA Call Center** at 877-GO4-HRSA (877-464-4772) between 9:00 am to 5:30 pm ET or email callcenter@hrsa.gov. You may be asked to provide a copy of the “Rejected with Errors” notification you received from Grants.gov.

You can check the status of your application(s) anytime after submission, by logging into Grants.gov using the black 'Applicants' link at the top of any page, and clicking on the 'Check Application Status' link.

If there are no errors, the application will be downloaded by HRSA. On successful download at HRSA, the status of the application will change to “Received by Agency” and you will receive an additional email from Grants.gov. Subsequently within two to three business days the status will change to “Agency Tracking Number Assigned.”

 **It is recommended that you check the status of your application in Grants.gov until the status is changed to “Agency Tracking Number Assigned”.**

2.5 Verify in HRSA Electronic Handbooks


For assistance in registering with or using HRSA EHBs, call 877-GO4-HRSA (877-464-4772) between 9:00 am to 5:30 pm ET or email callcenter@hrsa.gov.

 **Grant Project Director must be registered in HRSA EHBs and have access to the specific grant for which the noncompeting application is being submitted for further actions.**

2.5.1 Verify Status of Application

Once your application is received by HRSA, it will be processed to ensure that the application is submitted for the correct funding announcement, with the correct grant number and grantee organization. Upon this processing, which is expected to take up to two to three business days, HRSA will assign a unique tracking number to your application. This tracking number will be posted to Grants.gov and the status of your application will be changed to “Agency Tracking Number Assigned”. Note the HRSA tracking number and use it for all correspondence with HRSA. At this point, your application is ready for review and submission in HRSA EHBs.

You should also receive an email from HRSA EHBs confirming the successful receipt of your application at HRSA. The email is sent to the project director, authorizing official, point of contact for the application and the business official – all from the submitted application. The email is also sent to the current project director listed on the NGA. Because email is not always reliable, please check the HRSA EHBs or Grants.gov to see if the application is available for review in HRSA EHBs.

 **Because email is not reliable, check HRSA EHBs within two to three business days from submission within Grants.gov for availability of your application.**

2.5.2 Manage Access to Your Application

You must be registered in HRSA EHBs to get access to your application. To ensure that only the right individuals from the organization get access to the application, you must follow the process described earlier.

The project director, using the Administer feature in the grant handbook, must give the necessary privileges to the authorizing official and other individuals who will assist in the submission of the noncompeting continuation application. Project directors must also delegate the “Administer Grant Users” privilege to the authorizing official so that future administration can be managed by the authorizing official.

Once you have access to your grant handbook, use the “Noncompeting Continuations” link under the deliverables section to access your noncompeting application.

2.5.3 Check Validation Errors

HRSA EHBs will apply HRSA’s business rules to the application received through Grants.gov. All validation errors are recorded and displayed to the applicant. To view the validation errors use the ‘Grants.gov Data Validation Comments’ link on the application status page in HRSA EHBs.

2.5.4 Fix Errors and Complete Application

Applicants must review the errors in HRSA EHBs and make necessary changes. Applicants must also complete the detailed budget and other required forms in HRSA EHBs and assign an AO registered in HRSA EHBs to the application. HRSA EHBs will show the status of each form in the application package and all forms must be complete before submission.

2.5.5 Submit Application

To submit an application, you must have the 'Submit Noncompeting Continuation' privilege. This privilege must be given by the project director to the authorizing official or a designee. Once all forms are complete, the application can be submitted to HRSA.

You will have two weeks from the date the application was due in Grants.gov for submission of the remaining information in HRSA EHBs. The new due date will be listed in HRSA EHBs.

2.6 Submit Signed Face Page

After successful submission, the AO must print the face page of the application from the HRSA EHBs, sign it and mail it to HRSA at the address listed below:

HRSA Grants Application Center

Reference: Announcement Number: <Provide HRSA Announcement Number>

Reference: Grants.gov Tracking Number: <Provide Your Grants.gov Tracking Number>

910 Clopper Road, Suite 155 South

Gaithersburg, MD 20878

The face page must be received by HRSA within 5 business days from the date of submission in HRSA EHBs.

Once your signed face page is received by HRSA and saved with the application, you will receive an email receipt of application from HRSA.

Face page must be printed from HRSA EHBs and not from Grants.gov application.

3. Competing Application

3.1 Process Overview

Following is the process for submitting a competing application through Grants.gov:

1. HRSA will post all competing announcements on Grants.gov FIND (<http://grants.gov/search/>). Announcements are typically posted at the beginning of the fiscal year when HRSA releases its annual Preview, although program guidances are generally not available until later. For more information visit <http://www.hrsa.gov/grants>.
2. When program guidance is available, search for the announcement in Grants.gov Apply (<http://www.grants.gov/Apply>).
3. Download the application package and instructions from Grants.gov. The program guidance is also part of the instructions that must be downloaded.
4. Save a local copy of the application package on your computer and complete all the forms based on the instructions provided in the program guidance.
5. Submit the application package through Grants.gov. (Requires registration)
6. Track the status of your submitted application at Grants.gov until you receive a notification from Grants.gov that your application has been received by HRSA.
7. AO prints the application face page from the local copy, signs it and mails it to HRSA's Grant Application Center (GAC).
8. HRSA receives the signed face page and scans it into the system saving it with the electronic application.

3.2 Grantee Organization Needs to Register With Grants.gov (if not already registered) – See Appendix B

Grants.gov requires a **one-time** registration by the applicant organization. This is a three step process and should be completed by any organization wishing to apply for grant. If you do not complete this registration process you will not be able to submit an application. The registration process will require some time (anywhere from 5 business days to a month). Therefore, applicants or those considering applying at some point in the future should register immediately. Registration with Grants.gov provides the individuals from the organization the required credentials in order to apply.


If an applicant organization has already completed Grants.gov registration for another Federal agency, this section can be skipped.

For those applicant organizations still needing to register with Grants.gov, registration information can be found on the Grants.gov Get Started website (<http://www.grants.gov/GetStarted>). To be able to successfully register in Grants.gov, it is necessary that you complete all of the following required actions:

- Obtain an organizational Data Universal Number System (DUNS) number
- Register the organization with Central Contractor Registry (CCR)
- Identify the organization's E-Business POC (Point of Contact)
- Confirm the organization's CCR "Marketing Partner ID Number (M-PIN)" password
- Register an Authorized Organization Representative (AOR)
 - Obtain a username and password from the Grants.gov Credential Provider
 - Register the username and password with Grants.gov
 - Get authorized as an AOR by your organization

In addition, if an applicant does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. Beginning Oct. 30, 2005, the CCR also validates the EIN against Internal Revenue Service records, a step that will take one to two business days.

Please direct questions regarding Grants.gov registration to the Grants.gov Contact Center at Tel.: 1-800-518-4726. Contact Center hours of operation are Monday-Friday from 7:00 a.m. to 9:00 p.m. Eastern Time, excluding Federal holidays.

 **It is recommended that this registration process be completed at least two weeks prior to the submittal date of your organization's first Grants.gov submission.**

3.3 Apply through Grants.gov

3.3.1 Find Funding Opportunity

Search for announcements in Grants.gov **FIND** (<http://grants.gov/search/>) and select the announcement that you wish to apply for. Refer to the program guidance for eligibility criteria.

Please visit <http://www.hrsa.gov/grants> to read annual HRSA Preview.

 **All competing announcements should be available in Grants.gov FIND! When program guidance is release, announcements are made available in Grants.gov APPLY.**


3.3.2 Download Application Package

Download the application package and instructions. In order to view application package and instructions, you will also need to download and install the PureEdge Viewer (<http://www.grants.gov/DownloadViewer>). This small, free program will allow you to access, complete, and submit applications electronically and securely.

 **Please review the system requirements for PureEdge Viewer on the Grants.gov website.**


3.3.3 Complete Application

Complete the application using both the built-in instructions and the instructions provided in the program guidance. Ensure that you save a copy of the application on your local computer.

 **If you are applying for a competing continuation or a supplemental grant, ensure that you provide your 10-digit grant number (box 4b from NGA) in the Federal Award Identifier field (box 5b in SF424 or box 4 in SF424 R&R)**

Please direct questions regarding PureEdge to Grants.gov. Contact the Grants.gov Contact Center at Tel.: 1-800-518-4726. Contact Center hours of operation are Monday-Friday from 7:00 a.m. to 9:00 p.m. Eastern Time, excluding Federal holidays.

For assistance with program guidance related questions, please contact the program contact listed on the program guidance.


 **You can complete the application offline – you do not have to be connected to the Internet.**

3.3.4 Submit Application

The "Submit" button on the application package cover page will become active after you have downloaded the application package, completed all required forms, attached all required documents, and saved your application package. Click on the "Submit" button once you have done all these things and you are ready to send your completed application to Grants.gov.

Review the provided application summary to confirm that the application will be submitted to the program you wish to apply for. To submit, you will be asked to Log into Grants.gov. Once you have logged in, your application package will automatically be uploaded to Grants.gov. A confirmation screen will appear once the upload is complete. Note that a Grants.gov Tracking number will be provided on this screen. Please record this number so that you may refer to it for all subsequent help.

Please direct questions regarding application submission to the Grants.gov Contact Center at Tel.: 1-800-518-4726. Contact Center hours of operation are Monday-Friday from 7:00 a.m. to 9:00 p.m. Eastern Time, excluding Federal holidays.

 **You must be connected to the Internet and must have a Grants.gov username and password to submit the application package.**

3.3.5 Verify Status of Application

Once Grants.gov has received your submission, Grants.gov will send email messages to advise you of the progress of your application through the system. Over the next 24 to 48 hours, you should receive two emails. The first will confirm receipt of your application by the Grants.gov system ("Received"), and the second will indicate that the application has either been successfully validated ("Validated") by the system prior to transmission to the grantor agency or has been rejected due to errors ("Rejected with Errors").


In case of any errors, you must correct the application and resubmit it to Grants.gov. If you are unable to resubmit because the opportunity has since closed, **contact the Director of the Division of Grants Policy** via email at DGPClearances@hrsa.gov and thoroughly explain the situation; include a copy of the "Rejected with Errors" notification.

You can check the status of your application(s) anytime after submission, by logging into Grants.gov using the black 'Applicants' link at the top of any page, and clicking on the 'Check Application Status' link.

If there are no errors, the application will be downloaded by HRSA. On successful download at HRSA, the status of the application will change to "Received by Agency" and you will receive an additional email from Grants.gov.

Once your application is received by HRSA, it will be processed to ensure that the application is submitted for the correct funding announcement, with the correct grant number (if applicable), and applicant/grantee organization. Upon this processing, which is expected to take up to two to three business days, HRSA will assign a unique

tracking number to your application. This tracking number will be posted to the Grants.gov and the status of your application will be changed to “Agency Tracking Number Assigned”. Note the HRSA tracking number and use it for all correspondence with HRSA.

 **It is recommended that you check the status of your application in Grants.gov until the status is changed to “Agency Tracking Number Assigned”.**

3.4 Submit Signed Face Page

After successful submission in Grants.gov, the AO must print the face page of the application from Grants.gov, write the Grants.gov Tracking Number in Federal Entity Identifier field (box 5a in SF424 or box 4 in SF424 R&R), sign it and mail it to HRSA at the address listed below:

HRSA Grants Application Center

Reference: Announcement Number: <Provide HRSA Announcement Number>

Reference: Grants.gov Tracking Number: <Provide Your Grants.gov Tracking Number>


910 Clopper Road, Suite 155 South


Gaithersburg, MD 20878

The face page must be received by HRSA within 5 business days from the date of submission in Grants.gov.


Once your signed face page is received by HRSA and saved with the application, you will receive an email receipt of application from HRSA.

4. General Instructions for Application Submission

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

 **Failure to follow the instructions may make your application non-compliant. Non-compliant applications will not be given any consideration and the particular applicants will be notified.**

4.1 Narrative Attachment Guidelines

 **The following guidelines are applicable to both electronic and paper submissions (when allowed) unless otherwise noted.**

4.1.1 Font

Please use an easily readable serif typeface, such as Times Roman, Courier, or CG Times. The text and table portions of the application must be submitted in not less than 12 point and 1.0 line spacing. Applications not adhering to 12 point font requirements may be returned. Do not use colored, oversized or folded materials. For charts, graphs, footnotes, and budget tables, applicants may use a different pitch or size font, not less than 10 pitch or size font. However, it is vital that when scanned and/or reproduced, the charts are still clear and readable.

Please do not include organizational brochures or other promotional materials, slides, films, clips, etc.

4.1.2 Paper Size and Margins

For duplication and scanning purposes, please ensure that the application can be printed on 8 ½” x 11” white paper. Margins must be at least one (1) inch at the top, bottom, left and right of the paper. Please left-align text.

4.1.3 Names

Please include the name of the applicant and 10-digit grant number (if competing continuation, supplemental or noncompeting continuation) on each page.

4.1.4 Section Headings

Please put all section headings flush left in bold type.

4.1.5 Page Numbering

Electronic Submissions

For electronic submissions, applicants only have to number the electronic attachment pages sequentially, resetting the numbering for each attachment, i.e., start at page 1 for each attachment.

Do not number the standard OMB approved form pages.

Paper Submissions (When allowed)

Do not number the standard OMB approved forms. Please number each attachment page sequentially. Reset the numbering for each attachment. (Treat each attachment/document as a separate section.)

4.1.6 Allowable Attachment or Document Types

Electronic Submissions

The following attachment types are supported in HRSA EHBs. Even though grants.gov may allow you to upload any type of attachment, it is important to note that HRSA only accepts the following types of attachments:

- .DOC - Microsoft Word
- .RTF - Rich Text Format
- .TXT - Text
- .WPD - Word Perfect Document
- .PDF - Adobe Portable Document Format
- .XLS - Microsoft Excel

4.2 Application Content Order (Table of Contents)

When applications were submitted in paper, it was easy to direct the applicants to prepare a table of contents and make it as a part of the application. Applicants did not have any problem in preparing the package that included standard forms as well as attachments. All the pages were numbered sequentially. Preparation instructions were given in the program guidance. With the transition to electronic application receipt, this process has changed significantly. HRSA is using an approach that will ensure that regardless of the mode of submission (electronic or paper when exemptions are granted), all applications will look the same when printed for objective review.

HRSA uses two standard packages from Grants.gov.

SF 424 (otherwise known as 5161) – For service delivery programs

SF 424 R&R – For research and training programs (programs previously using the 398 or the 6025 and 2590 application packages)

For each package HRSA has defined a standard order of forms and that order is available within the program guidance. The program guidance may also provide applicants with explicit instructions on where to upload specific documents.

If you are applying on paper (when allowed), you must use the program guidance for the order of the forms and all other applicable guidelines.

4.3 Page Limit

HRSA prints your application for review regardless of whether it is submitted electronically or by paper (when allowed).

When your application is printed, the narrative documents may not exceed 80 pages in length unless otherwise stated in the program guidance. These narrative documents include the abstract, project and budget narratives, and any other attachments such as appendices, letters of support required as a part of the guidance. This 80 page limit

does not include the OMB approved forms. Note that some program guidances may require submission of OMB approved program specific forms as attachments. These attachments will not be included in the 80 page limit.

Applicants must follow the instructions provided in this section and ensure that they print out all attachments on paper and count the number of pages before submission.

Applications, whether submitted electronically or on paper, that exceed the specified limits will be deemed non-compliant. Non-compliant competing applications will not be given any consideration and the particular applicants will be notified. Non-compliant noncompeting applications will have to be resubmitted to comply with the page limits.

5. Customer Support Information

5.1.1 Grants.gov Customer Support

Please direct ALL questions regarding Grants.gov to Grants.gov Contact Center at Tel.: 1-800-518-4726. Contact Center hours of operation are Monday-Friday from 7:00 a.m. to 9:00 p.m. Eastern Time, excluding Federal holidays.

Please visit the following support URL for additional material on Grants.gov website.

<http://www.grants.gov/CustomerSupport>

5.1.2 HRSA Call Center

For assistance with or using HRSA EHBs, call 877-GO4-HRSA (877-464-4772) between 9:00 am to 5:30 pm ET or email callcenter@hrsa.gov.

Please visit HRSA EHBs for online help. Go to:

<https://grants.hrsa.gov/webexternal/home.asp> and click on 'Help'

5.1.3 HRSA Program Support

For assistance with program guidance related questions, please contact the program contact listed on the program guidance. Do not call the program contact for technical questions related to either Grants.gov or HRSA EHBs.

6. FAQs

6.1 Software

6.1.1 What are the software requirements for using Grants.gov?

Applicants will need to download the PureEdge viewer. Grants.gov website provides the following information:

System Requirements:

For PureEdge Viewer to function properly, your computer must meet the following system requirements:

Windows 98, ME, NT 4.0, 2000, XP

500 Mhz processor

128 MB of RAM

40 MB disk space

Web browser: Internet Explorer 5.01 or higher, Netscape Communicator 4.5 - 4.8, Netscape 6.1, 6.2, or 7

If you do not have a Windows operating system, you will need to use a Windows Emulation program.

Please visit <http://www.grants.gov/DownloadViewer> for all details and any updates.

6.1.2 Why can't I download PureEdge Viewer onto my machine?

Depending on your organization's computer network and security protocols you may not have the necessary permissions to download software onto your workstation. Contact your IT department or system administrator to download the software for you or give you access to this function.

6.1.3 I have heard that Grants.gov is not Macintosh compatible. What do I do if I use only a Macintosh?

Grants.gov is aware of the issues facing Macintosh users who apply for Federal grants electronically. Grants.gov has provided the following response regarding this issue on its website at <http://www.grants.gov/MacSupport>:

Grants.gov recognizes that support to users of Non-Windows operating systems and the PureEdge Viewer is often required across a distinct segment of the grant applicant community. Although at this time, the PureEdge Viewer is only available for Windows based installs, Grants.gov offers support for Non-Windows platforms.

Grants.gov is working with PureEdge in the development of a Non-Windows compatible viewer. PureEdge has committed to providing a platform independent viewer by November 2006. Information related to the Non-Windows compatible viewer will be posted to this webpage (<http://www.grants.gov/MacSupport>). Please bookmark this page and return at your convenience for more details.

Grants.gov and NIH have partnered to provide free access to Citrix servers for Macintosh Users who are looking for an alternative to using PC emulation software with the PureEdge forms. A Citrix server connection allows Macintosh users to remotely launch a Windows session on their own machines by using the free Citrix client application. Applicants will need to download and install the free Citrix client application in order to work. This service is now available for use.

Grants.gov website states:

Beginning December 20, 2005, non-Windows users will be able to download and complete the PureEdge forms by taking advantage of the free Citrix server. Non-Windows users are also able to submit completed grant applications via the Citrix environment.

For details, please visit <http://www.grants.gov/MacSupport>

6.1.4 What are the software requirements for HRSA EHBs?

HRSA EHBs can be accessed over the Internet using Internet Explorer (IE) v5.0 and above and Netscape 4.72 and above. HRSA EHBs are 508 compliant.

IE 6.0 and above is the recommended browser.

HRSA EHBs use pop-up screens to allow users to view or work on multiple screens. Ensure that your browser settings allow for pop-ups.

In addition, to view attachments such as Word and PDF, you will need appropriate viewers.

6.1.5 What are the system requirements for using HRSA EHBs on a Macintosh computer?

Mac users are requested to download the latest version of Netscape for their OS version. It is recommended that Safari v1.2.4 and above or Netscape v7.2 and above be used.

Note that Internet Explorer (IE) for Mac has known issues with SSL and Microsoft is no longer supporting IE for Mac. HRSA EHBs do not work on IE for Mac.

In addition, to view attachments such as Word and PDF, you will need appropriate viewers.

6.2 Application Receipt

6.2.1 What will be the receipt date--the date the application is stamped as received by Grants.gov or the date the data is received by HRSA?

Competing Submissions:

The submission/receipt date will be the date the application is received by Grants.gov.

Noncompeting Submissions:

The submission/receipt date will be the date the application is submitted in HRSA EHBs.

6.2.2 When do I need to submit my application?

Competing Submissions:

Applications must be submitted to Grants.gov by 8 PM ET on the due date.

Noncompeting Submissions:

Applications must be submitted to Grants.gov by 8 PM ET on the due date.

Applications must be verified and submitted in HRSA EHBs by 5:00 PM ET on the due date. (2 weeks after the due date in Grants.gov) Refer to the program guidance for specific dates.

6.2.3 What emails can I expect once I submit my application? Is email reliable?

Competing Submissions:

When you submit your noncompeting application in Grants.gov, it is first received and validated by Grants.gov. Typically, this takes a few hours but it may take up to 48 hours during peak volumes. You should receive two emails from Grants.gov.

The first will confirm receipt of your application by the Grants.gov system ("Received"), and the second will indicate that the application has either been successfully validated ("Validated") by the system prior to transmission to the grantor agency or has been rejected due to errors ("Rejected with Errors").

Subsequently, the application will be downloaded by HRSA. This happens within minutes of when your application is successfully validated by Grants.gov and made available for HRSA to download. On successful download at HRSA, the status of the application will change to "Received by Agency" and you will receive another email from Grants.gov.

You will receive an additional email from HRSA once your signed face page is received and processed. This email serves as the official receipt for your application.

Because email is not reliable, you must check the respective systems if you do not receive any emails within the specified timeframes.

Noncompeting Submissions:

When you submit your noncompeting application in Grants.gov, it is first received and validated by Grants.gov. Typically, this takes a few hours but it may take up to 48 hours during peak volumes. You should receive two emails from Grants.gov.

Subsequently, the application will be downloaded by HRSA. This happens within minutes of when your application is successfully validated by Grants.gov and made available for HRSA to download. On successful download at

HRSA, the status of the application will change to “Received by Agency” and you will receive another email from Grants.gov.

Subsequently, it is processed by HRSA to ensure that the application is submitted for the correct funding announcement, with the correct grant number and grantee organization. This may take up to 3 business days. At this point you will receive an email from HRSA confirming the successful receipt of your application and asking the PD and AO to review and resubmit the application in HRSA EHBs.

You will receive an additional email from HRSA once your signed face page is received and processed. This email serves as the official receipt for your application.

Because email is not reliable, you must check the respective systems if you do not receive any emails within the specified timeframes.

 For more information refer to sections 2.4 and 2.5 in this guide

6.2.4 If a resubmission is required because of Grants.gov system problems, will these be considered "late"?

Competing Submissions:

No. But you must **contact the Director of the Division of Grants Policy** via email at DGPClearances@hrsa.gov and thoroughly explain the situation. Include a copy of the “Rejected with Errors” notification you received from Grants.gov.

Noncompeting Submissions:

No. But you must **contact the HRSA Call Center** at 877-GO4-HRSA (877-464-4772) between 9:00 am to 5:30 pm ET or email callcenter@hrsa.gov. You may be asked to provide a copy of the “Rejected with Errors” notification you received from Grants.gov.

6.3 Application Submission

6.3.1 How can I make sure that my electronic application is presented in the right order for objective review?

Follow the instructions provided in section 4.2 to ensure that your application is presented in the right order and is compliant with all the requirements.

6.4 Grants.gov

For a list of frequently asked questions and answers maintained by Grants.gov please visit the following URL:

http://www.grants.gov/GrantsGov_UST_Grantee/!SSL!/WebHelp/GrantsGov_UST_Grantee.htm#index.html

Appendix B – Registering and Applying Through Grants.gov

Prepare to Apply through Grants.gov:

HRSA, in providing the grant community a single site to Find and Apply for grant funding opportunities, is requiring applicants for this funding opportunity to apply electronically through Grants.gov. By using Grants.gov you will be able to download a copy of the application package, complete it off-line, and then upload and submit the application via the Grants.gov site. You may not e-mail an electronic copy of a grant application to us.

Please understand that we will not consider additional information and/or materials submitted after your initial application. You must therefore ensure that all materials are submitted together.

Note: Except in rare cases, paper applications will NOT be accepted for this grant opportunity. If you believe you are technologically unable to submit an on-line application you MUST contact the Director of the Division of Grants Policy, at DGPClearances@hrsa.gov and explain why you are technologically unable to submit on-line. Make sure you specify the announcement number you are requesting relief for. HRSA and its Grants Application Center (GAC) will only accept paper applications from applicants that received prior written approval.

In order to apply through Grants.gov the Applicant must register with Grants.gov. This is a three step process that must be completed by any organization wishing to apply for a grant opportunity. The registration process will require some time. Therefore, applicants or those considering applying at some point in the future should register **immediately**. Registration in Grants.gov does not require the organization to apply for a grant; it simply provides the organization the required credentials so that the organization may apply for a grant in the future. Registration is required only once.

REGISTRATION:

GET STARTED NOW AND COMPLETE THE ONE-TIME REGISTRATION PROCESS TO BEGIN SUBMITTING GRANT APPLICATIONS AS SOON AS YOU READ THIS.

You don't need to be registered to search or to begin selecting, downloading and completing grant applications. Registration is required to submit applications. Therefore, it is essential that your organization be registered prior to attempting to submit a grant application or your organization will not be able to do so. **Be sure to complete the process early as the registration process may take some time (anywhere from 5 days to 1 month).**

There are three steps to the registration process:

- Step 1: Register your organization
- Step 2: Register yourself as an Authorized Organization Representative
- Step 3: Get authorized by your organization to submit grants

These instructions will walk you through the three basic registration steps. Additional assistance is available at Grants.gov at www.grants.gov. Individual assistance is available at <http://www.grants.gov/Support> or 1-800-518-4726. Grants.gov also provides a variety of support options through online Help including Context-Sensitive Help, Online Tutorials, FAQs, Training Demonstration, User Guide, and Quick Reference Guides.

Follow this checklist to complete your registration—

1. Register Your Organization

- Obtain your organization's Data Universal Number System (DUNS) number
- Register your organization with Central Contractor Registry (CCR)
- Identify your organization's E-Business POC (Point of Contact)

- Confirm your organization's CCR "Marketing Partner ID Number (M-PIN)" password

2. Register Yourself as an Authorized Organization Representative (AOR)

- Obtain your username and password
- Register your username and password with Grants.gov

3. Get Yourself Authorized as an AOR

- Contact your E-Business POC to ensure your AOR status
- Log in to Grants.gov to check your AOR status

The Grants.gov/Apply feature includes a simple, unified application process to enable applicants to apply for grants online. The information applicants need to understand and execute the steps is at <http://www.grants.gov/GetStarted>. Applicants should read the Get Started steps carefully. The site also contains registration checklists to help you walk through the process. HRSA recommends that you download the checklists and prepare the information requested before beginning the registration process. Reviewing information required and assembling it before beginning the registration process will save you time and make the process faster and smoother.

REGISTER YOUR ORGANIZATION

Before you can apply for a grant via Grants.gov, your organization must obtain a Data Universal Number System (DUNS) number and register early with the Central Contractor Registry (CCR).

Obtain your organization's DUNS number

A DUNS number is a unique number that identifies an organization. It has been adopted by the Federal government to help track how Federal grant money is distributed. Ask your grant administrator or chief financial officer to provide your organization's DUNS number.

-How do you do it? If your organization does not have a DUNS number, call the special Dun & Bradstreet hotline at 1-866-705-5711 to receive one free of charge.

- How long will this take? You will receive a DUNS number at the conclusion of the phone call.

Register your organization with CCR

The CCR is the central government repository for organizations working with the Federal government. Check to see if your organization is already registered at the CCR website. If your organization is not already registered, identify the primary contact who should register your organization.

When your organization registers with CCR, it will be required to designate an E-Business Point of Contact (E-Business POC). The designee authorizes individuals to submit grant applications on behalf of the organization and creates a special password called a Marketing Partner ID Number (M-PIN) to verify individuals authorized to submit grant applications for the organization.

-How do you do it? Visit the CCR website at <http://www.ccr.gov>. Check whether your organization is already registered or register your organization right online. Be certain to enter an MPIN number during this process as this is an optional field for the CCR registration but mandatory for Grants.gov.

- How long will this take? It may take a few days for you to collect the information needed for your organization's registration, but once you finish the registration process, you can move on to Step 2 the very next business day. Note it will take up to a month for the total registration- therefore this should be done as soon as possible.

GET AUTHORIZED as an AOR by Your Organization

The registration process is almost complete. All that remains is the final step —getting authorized. Even though you have registered, your E-Business POC must authorize you so Grants.gov will know that you are verified to submit applications.

- Obtain your E-Business POC authorization

After your Authorized Organizational Representative (AOR) profile is completed, your organization's E-Business POC will receive an email regarding your requested AOR registration, with links and instructions to authorize you as an AOR.

- **How do you do it?** Instruct your E-Business POC to login to Grants.gov at <http://www.grants.gov/ForEbiz> and enter your organization's DUNS number and M-PIN. They will select you as an AOR they wish to authorize and you will be verified to submit grant applications.

- **How long will this take?** It depends on how long it takes your E-Business POC to log in and authorize your AOR status. You can check your AOR status by logging in to Grants.gov at <http://www.grants.gov/ForApplicants>.

REGISTER YOURSELF as an Authorized Organization Representative (AOR)

Once the CCR Registration is complete, your organization is finished registering. You must now register yourself with Grants.gov and establish yourself as an AOR, an individual authorized to submit grant applications on behalf of your organization. There are two elements required to complete this step — both must be completed to move onto Step 3.

1. Obtain your username and password

In order to safeguard the security of your electronic information, and to submit a Federal grant application via Grants.gov, you must first obtain a username and password from the Grants.gov Credential Provider.

- **How do you do it?** Just register with Grants.gov's Credential Provider at <http://www.grants.gov/Register1>. You will need to enter your organization's DUNS number to access the registration form. Once you complete the registration form you will be given your username and you will create your own password.

- **How long will this take?** Same day. When you submit your information you will receive your username and be able to create your password.

2. Register with Grants.gov

Now that you have your username and password, allow about 30 minutes for your data to transfer from the Credential Provider, then you must register with Grants.gov to set up a short profile.

> **How do you do it?** Simply visit <http://www.grants.gov/Register2> to register your username and password and set up your profile. Remember, you will only be authorized for the DUNS number which you register in your Grants.gov profile.

> **How long will this take?** Same day. Your AOR profile will be complete after you finish filling in the profile information and save the information at Grants.gov.

You have now completed the registration process for Grants.gov. If you are applying for a new or competing continuation you may find the application package through Grants.gov FIND. If you are filling out a non-competing continuation application you must obtain the announcement number through your program office, and enter this announcement number in the search field to pull up the application form and related program guidance. Download the required forms and enter your current grant number in the appropriate field to begin the non-competing continuation application which you will then upload for electronic submittal through Grants.gov. For continuation applications which require submittal of

performance measures electronically, instructions are provided in the program guidance on how to enter the HRSA electronic handbooks to provide this information.

How to submit an electronic application to HRSA via Grants.gov/Apply

a. Applying using Grants.gov. Grants.gov has a full set of instructions on how to apply for funds on its website at <http://www.grants.gov/CompleteApplication>. The following provides simple guidance on what you will find on the Grants.gov/Apply site. Applicants are encouraged to read through the page entitled, "Complete Application Package" before getting started. See Appendix A for specific information.

b. Customer Support. The grants.gov website provides customer support via (800) 518-GRANTS (this is a toll-free number) or through e-mail at support@grants.gov. The customer support center is open from 7:00 a.m. to 9:00 p.m. Eastern time, Monday through Friday, except federal holidays, to address grants.gov technology issues. For technical assistance to program related questions, contact the number listed in the Program Section of the program you are applying for.

Timely Receipt Requirements and Proof of Timely Submission

a. Electronic Submission. All applications must be received by www.grants.gov/Apply by 8:00 P.M. Eastern Time on the due date established for each program.

Proof of timely submission is automatically recorded by Grants.gov. An electronic time stamp is generated within the system when the application is successfully received by Grants.gov. The applicant will receive an acknowledgement of receipt and a tracking number from Grants.gov with the successful transmission of their application. Applicants should print this receipt and save it, along with facsimile receipts for information provided by facsimile, as proof of timely submission. When HRSA successfully retrieves the application from Grants.gov, Grants.gov will provide an electronic acknowledgment of receipt to the e-mail address of the AOR. Proof of timely submission shall be the date and time that Grants.gov receives your application.

Applications received by grants.gov, after the established due date and time for the program, will be considered late and will not be considered for funding by HRSA. HRSA suggests that applicants submit their applications during the operating hours of the Grants.gov Support Desk, so that if there are questions concerning transmission, operators will be available to walk you through the process. Submitting your application during the Support Desk hours will also ensure that you have sufficient time for the application to complete its transmission prior to the application deadline. Applicants using dial-up connections should be aware that transmission should take some time before Grants.gov receives it. Grants.gov will provide either an error or a successfully received transmission message. The Grants.gov Support desk reports that some applicants abort the transmission because they think that nothing is occurring during the transmission process. Please be patient and give the system time to process the application. Uploading and transmitting many files, particularly electronic forms with associated XML schemas, will take some time to be processed.

Note the following additional information regarding submission of all HRSA applications through Grants.gov:

- You must submit all documents electronically, including all information typically included on the SF424 and all necessary assurances and certifications.
- Your application must comply with any page limitation requirements described in this program announcement.
- After you electronically submit your application, you will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number. HRSA will retrieve your application from Grants.gov.

Online applications are required to submit ONLY one form in signed hard copy: the SF-424/5161 Face Sheet, since all other elements of the application have been captured and transmitted electronically. This face page should be sent to HRSA's Grants Application Center at:

The HRSA Grants Application Center
The Legin Group, Inc.
Attn: *[provide Grants.gov Tracking Number]*
Program Announcement No. HRSA-07-077
CFDA No. 93.134
910 Clopper Road, Suite 155 South
Gaithersburg, MD 20878
Telephone: 877-477-2123

Formal Submission of the Electronic Application

Applications completed online are considered formally submitted when the Authorizing Official electronically submits the application to HRSA through Grants.gov. However, to complete the submission requirements, a hard-copy of the SF-424/5161 Face Sheet must be printed, signed, and submitted to the HRSA Grants Application Center. For competitive applications, the SF-424/5161 must be printed from Grants.gov.

For an online application, the signed SF-424/5161 must be sent to the HRSA GRANTS APPLICATION CENTER at the above address and received by HRSA by no later than five days after the date of submission in Grants.gov.

Competitive applications will be considered as having met the deadline if: (1) the application has been successfully transmitted electronically by your organization's Authorizing Official through Grants.gov on or before the deadline date and time, and (2) the signed SF-424/5161 Face Sheet is received by HRSA no later than five days after submission in Grants.gov.

Performance Measures for Competitive Applications

Many HRSA guidances include specific data forms and require performance measure reporting. If the completion of performance measure information is indicated in this guidance, successful applicants receiving grant funds will be required, within 30 days of the Notice of Grant Award (NGA), to register in HRSA's Electronic Handbooks (EHBs) and electronically complete the program specific data forms that appear in this guidance. This requires the provision of budget breakdowns in the financial forms based on the grant award amount, the project abstract and other grant summary data, and objectives for the performance measures.

Performance Measures for Non-Competing Continuation Applications

For applications which require submittal of performance measures electronically through the completion of program specific data forms, instructions will be provided both in the program guidance and through an e-mail, notifying grantees of their responsibility to provide this information, and providing instructions on how to do so.

Appendix C: Instructions for the SF424 R&R (Research and Related)

This application form has replaced the 6025 training application form and the 398 application form. The 424 R&R is now used for all HRSA training and research programs.

INSTRUCTIONS FOR THE APPLICATION FACE PAGES

Below are detailed instructions for the completion of the 424 R&R form:

Field	Instructions
1.	Select Type of Submission : Check the appropriate type from the submission options. Select Application for all HRSA grant programs
2.	Date Submitted : Enter the date the application is submitted to the Federal agency.
3.	Date Received by State : State Use Only (if applicable)
4.	Federal Identifier : New Project Applications should leave this field blank. If this is a Continuation application (competing or non-competing) or a Supplement, enter your grant number located on your Notice of Grant Award (NGA).
5.	<p>Applicant Information: All items in bold are required fields and must be completed Enter your Organization's DUNS Number (received from Dun and Bradstreet), Enter the Legal Name, Applicant Department (if applicable) and Division (if applicable) who will undertake the assistance activity. In Street 1 enter the first line of the street address of your organization. In Street2 enter the second line of your organization, if applicable. Enter the City, County and State, Zip Code and Country where your organization is located. Enter the Person to be Contacted on Matters Involving the Application:</p> <p>This is the POINT OF CONTACT, the person to be contacted for the matters pertaining to this specific application (i.e. principle investigator, project director, other). Enter the Prefix, First Name, Middle Name and Last Name and Suffix (if applicable) of the person to be contacted on matters relating to this application. Enter the Phone and Fax number as well as the E-MAIL address of this person. These are all required fields.</p>
6.	<p>Employer Identification (EIN)/ (TIN) Enter the 9 Digit Employer Identification Number as Assigned by the Internal Revenue Services.</p>
7.	<p>Type of Applicant : Select the appropriate letter from one of the following:</p> <ul style="list-style-type: none"> A. State Government B. County Government C. City or Township Government D. Special District Government E. Independent School District F. State Controlled Institution of Higher Education G. Native American Tribal Government (Federally Recognized) H. Public/Indian Housing Authority I. Native American Tribal Organization (other than Federally recognized) J. Nonprofit with 501C3 IRS status (other than Institute of Higher Education) K. Nonprofit without 501C3 IRS status (other than Institute of Higher Education) L. Private Institution of Higher Education M. Individual N. For Profit Organization(other than small business) O. Small Business P. Other (specify) <p>Women Owned: Check if you are a woman owned small business(51% owned/controlled and operated by a woman/women) Socially and Economically Disadvantaged: Check if you are a socially and economically disadvantaged small business, as determined by the U.S. SBA pursuant to Section 8(a) of the SBA U.S.C.637(a).</p>
8.	<p>Type of Application: Select the Type from the following list : - New: A new assistance award</p>

	<p>- Resubmission (not applicable to HRSA)</p> <p>- Renewal – An application for a competing continuation – this is a request for an extension for an additional funding/budget period for a project with a projected completion.</p> <p>-Continuation: A non-competing application for an additional funding/budget period for a project within a previously approved projected period</p> <p>- Revision: Any change in the Federal Governments financial obligation or contingent liability from an existing obligation. Indicate the Type of Revision by checking the appropriate box: A. Increase in Award (supplement, competing supplement) B. Decrease Award C. Increase Duration D. Decrease Duration E. Other (Enter text to Explain)</p> <p>Is Application being submitted to Other Agencies: Indicate by checking YES or NO if the application is being submitted to HRSA only.</p> <p>What other Agencies: Enter Agency Name (if applicable)</p>
9.	Name of Federal Agency: Enter the Name of the Federal Agency from which assistance is being requested
10.	Catalogue of Federal Domestic Assistance Number (CFDA): Use the CFDA Number found on the front page of the program guidance and associated Title of the CFDA (if available).
11.	Descriptive Title of Applicant’s Project: Enter a brief descriptive title of the project. A continuation or revision must use the same title as the currently funded project.
12.	Areas Affected by Project: List only the largest political Entities affected by the project (ex. states, counties, cities)
13.	Proposed Project: Enter the project Start Date of the project in the Start Date Field and the project Ending Date in the Ending Date Field. (ex.11/01/2005 to 10/31/2008)
14.	Congressional District Applicant and Congressional District Project: Enter your Congressional District(s) in Applicant Field. Enter the Congressional District (s) of Project, the primary site where the project will be performed. (http://www.gpoaccess.gov/cdirectory/browse-cd-05.html)
15.	Project Director/Principal Investigator Contact Information : All items in bold are required fields and must be completed Enter the Prefix, First Name, Middle Name and Last Name and Suffix (if applicable) of the Project Director/Principle Investigator (PD/PI) for the project. Enter the Title of the PD/PI and the name of the organization of the PD/PI. Enter the name of the primary organization Department and Division of the PD/PI. In Street 1 enter the first line of the street address of the PD/PI for the project. In Street2 enter the second line of the street address for the PD/PI, if applicable. Enter the City, County and State, Zip Code and Country of the PD/PI. Enter the Phone and Fax number as well as the E-MAIL address of this person. These are all required fields.
16.	Estimated Project Funding: a. Total Estimated Project Funding Enter the total Federal Funds requested for the BUDGET PERIOD for which you are applying. Enter only the amount for the year you are applying, NOT the amount for the entire project period. b. Total Federal and Non-Federal Funds: Enter the total Federal and non-Federal funds for the BUDGET PERIOD for which you are applying. c. Estimated Program Income: Identify any Program Income for the BUDGET PERIOD.
17.	Is Application Subject to Review by State Executive Order 12372 Process: If YES: Check the YES box if the announcement indicates that the program is covered under State Executive Order 12372. If NO: Place a check in the NO box.
18.	Complete Certification Check the “I agree” box to attest to acceptance of required certifications and assurances listed at the end of the Application.
19.	Authorized Representative (Authorizing Official - This is the person who has the authority to sign the application for the organization) All items in bold are required fields and must be completed Enter the name of Authorized Representative/Authorizing Official. Enter the Prefix, First Name, Middle Name and Last Name and Suffix (if applicable) of the Authorized Representative (AR) or Authorizing Official (AO). Enter the Title of the Authorized Representative and the organization

	<p>of the AR/AO. Enter the name of the primary organization Department and Division of the AO. In Street1 enter the first line of the street address of the AR/AO for the project. In Street2 enter the second line of the street address for the AR/AO, if applicable. Enter the City, County and State, Zip Code and Country of the AR/AO. Enter the Phone and Fax number as well as the E-MAIL address of AR/AO this person. These are all required fields .</p> <p>Date Signed: If you are submitting this electronically please print off a copy of the face/cover pages of the application, sign and send them to HRSA’s Grants Application Center (GAC) –(See the program guidance for the GAC’s address)</p> <p>Note: Applicant applying in paper must send their entire grant application with the signed face/cover pages to the GAC</p>
20.	<p>Pre-Application This is Not applicable to HRSA. A limited number of HRSA programs require a Letter of Intent which is different from a preapplication. Information required and the process for submitting such a Letter of Intent is outlined in the funding opportunity announcements for those programs with such a requirement. .</p>

INSTRUCTIONS FOR 5161 CHECKLIST (This is used for the 424 R&R as well)

Field	Instructions
Type of Application	<p>Check one of the boxes corresponding to one of the following types:</p> <ul style="list-style-type: none"> - New: A new application is a request for financial assistance for a project or program not currently receiving DHHS support. -Non competing Continuation: A non-competing application for an additional funding/budget period for a project within a previously approved project period - Competing Continuation (same as Renewal from 424R&R face page) –this is a request for an extension of support for an additional funding/budget period for a project with a projected completion. - Supplemental (same as Revision from 424 R&R face page) An application requesting a change in the Federal Governments financial obligation or contingent liability from an existing obligation.
Part A	Leave this Section Blank
Part B	Leave this Section Blank
Part C	In the Space Provided below, please provide the requested information
Business Official to be notified if an award is to be made	<p>Enter the name of Business Official to be notified if an award is to be made. Enter the Prefix, First Name, Middle Name and Last Name and Suffix (if applicable) of the Business Official and the organization. Enter the Address Street1 enter the first line of the street address of the Business Official. In Street2 enter the second line of the street address for the AR/AO, if applicable. Enter the City, County and State, Zip Code and Country of the business official. Enter the Telephone and Fax number as well as the E-MAIL address of Business Official. Enter the Applicant Organizations 12 Digit DHHS EIN (if already assigned) – This should be the same information as supplied in file number 5 of the 424 R&R face page .</p>
Project Director/Principle Investigator designated to direct the proposed project	<p>Enter the name of Project Director/Principle Investigator (PD/PI) – this should be the same information as supplied on the 424 R & R face page field number 15. Enter the Prefix, First Name, Middle Name and Last Name and Suffix (if applicable). Enter the name of the primary organization and Address: Street1 enter the first line of the street address of the AR/AO for the project. In Street2 enter the second line of the street address for the AR/AO, if applicable. Enter the City, County and State, Zip Code and Country of the PD/PI. Enter the Telephone Number, E-Mail and Fax number. DO NOT enter the social security number. Enter the highest degree earned for the PD/PI.</p>

INSTRUCTIONS FOR R&R SENIOR/KEY PERSON PROFILE

Starting with the PD/PI, provide a profile for each senior/key person proposed. Unless otherwise specified in an agency announcement senior key personnel are defined as all individuals who contribute in a substantive, measurable way to the execution of the project or activity whether or not salaries are requested. Consultants should be included if they meet this definition. For each of these individuals a Biosketch should be attached which lists the individual's credentials/degrees.

Field	Instruction
Prefix	Ex. Mr., Ms. Mrs. Rev. Enter the Prefix for the Individual identified as a key person for the project. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated with the prefix for the project director identified on the face page of the 424 R&R.
First Name	This is the first (given) name of the Individual identified as a key person for the project. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated with the name of the project director identified on the face page of the 424 R&R.
Middle Name	This is the middle name of the Individual identified as a key person for the project. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated with the name of the project director identified on the face page of the 424 R&R.
Last Name	This is the last name of the Individual identified as a key person for the project. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated with the last name of the project director identified on the face page of the 424 R&R.
Suffix	Enter the Suffix (Ex. Jr., Sr., PhD.) for the Individual identified as a key person for the project. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated with the prefix for the project director identified on the face page of the 424 R&R.
Position/Title	Enter the Title for the Individual identified as a key person for the project. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated with the Title for the project director identified on the face page of the 424 R&R.
Department	This is the name of the primary organizational department, service, laboratory, or equivalent level within the organization for the Individual identified as a key person for the project. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated with the Department for the project director identified on the face page of the 424 R&R.
Organization Name	This is the name of the organizational for the Individual identified as a key person for the project. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated with the Organization Name for the project director identified on the face page of the 424 R&R.
Division	This is the primary organizational division, office, or major subdivision of the individual. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated with the Division for the project director identified on the face page of the 424 R&R.
Street1	This is the first line of the street address for the individual identified as a key/senior person. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated with the Street address for the project director identified on the face page of the 424 R&R.
Street 2	This is the second line of the street address (if applicable) for the individual identified. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated with the second line of the Street address (if applicable) for the project director identified on the face page of the 424 R&R
City	Enter the city where the key/senior person is located. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated.
County	Enter the County where the key/senior person is located. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated.
State	Enter the state where the key/senior person is located. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated
ZIP Code	Enter the Zip Code where the key/senior person is located. If this is the entry for the Project

	Director and you are submitting electronically this field will be prepopulated
Phone Number	Enter the daytime phone number for the senior/key person. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated
Fax Number	Enter the fax number for the senior/key person. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated
Email address	Enter the email address for the senior/key person. If this is the entry for the Project Director and you are submitting electronically this field will be prepopulated- This is a required field
Credential e.g. agency login	Leave this field blank
Project Role	Enter the project role from the list below 1. Project Director (PD)/Principle Investigator(PI) 2. Co- PD/Co- PI 3. Faculty 4. Post Doctoral 5. Post Doctoral Associate 6. Other Professional 7. Graduate Student 8. Undergraduate Student 9. Technician 10. Consultant 11. Other (Specify)
Other Project Role Category	Complete if you selected "Other" as a project role. For example, Engineer, social worker.
Attach Biographical Sketch	Provide a biographical sketch for the PD/PI or Senior Key Person identified. For each of these individuals a Biosketch should be attached which lists the individual's credentials/degrees. Recommended information includes: education and training, research and professional and synergistic activities. Save the information in a single file and attach by clicking Add attachment –if applying electronically
Attach Current & Pending Support	Follow the individual program guidance pertaining to this issue. If current and pending support on level of effort documentation is required, please attach accordingly.

INSTRUCTIONS FOR R&R PROJECT PERFORMANCE SITE LOCATION(S) FORM

Indicate the primary site/sites where the work or activity will occur. If a portion of the project is at any other location(s), identify it in the section provided. If more than eight project/performance site locations are proposed, provide the information in a separate file and attach these in a file in the space provided at the bottom of the form. If applying in paper add this information as part of the appendix.

Enter the Primary Performance Site first. Add all other performance sites in the space provided.

Field name	Instructions
Organization Name	Enter the Name of the Performance Site/Organization
Street 1	Enter the first line of the street address of the performance site location
Street 2	Enter the second line of the street address of the performance site location, if applicable
City	Enter the city of the performance site.
County	Enter the county where the performance site is located.
State	Select from the list of States or enter the State/province in which the performance site is located
Zip Code	Enter the zip code of the performance sit location
Country	Enter the country of the performance site from the list

INSTRUCTIONS FOR R&R BUDGET

Section A & B

SECTION A

Field Name	Instructions
Organizational DUNS	Enter the DUNS or DUNS +4 number of your organization. For applicants applying electronically, this field is pre-populated from the R&R SF424 Cover Page.
Budget Type	Check the appropriate block. Check Project if the budget requested is for the primary applicant organization. Check Subaward/consortium organizations (if applicable). Separate budgets are usually required only for Subaward Budgets and are not allowed by HRSA unless legislatively authorized or requested in the program application guidance. Use the R&R Subaward Budget Attachment and attach as a separate file on the R&R Budget Attachment(s) form.
Enter Name of Organization	Enter the name of your organization
Start Date	Enter the requested Start Date of Budget Period
End Date	Enter the requested End Date of the Budget Period (these should cover 1 full year/12 months)
Budget Period	Identify the specific budget period (1 for first year of the grant, 2 for second year of the grant, 3 for third etc.)
A. Senior/Key Person	Enter the Prefix, First/(Given) name, Middle name (if applicable), Last Name and Suffix of the senior/key person
Project Role	Enter the project role of the Senior/Key person.
Base Salary (\$)	Enter the annual compensation paid by the employer for each Senior/Key person. This includes all activities such as research, teaching, patient care. etc.
Cal. Months	Enter the number of Calendar months devoted to the project in the applicable box for each project role category
Acad. Months	Enter the number of academic year months devoted to the project in the applicable box for each project role category (If your institution does not use a 9 month academic period, indicate your institution’s definition of academic year in the budget justification)
Sum. Months	Enter the number of summer months devoted to the project in the applicable box for each project role category (If your institution does not use a 3 month summer period, indicate your institution’s definition of summer period in the budget justification)
Requested Salary (\$)	Regardless of the number of months being devoted to the project, indicate only the funds being requested to cover the amount of salary/wages for each senior/key person for this budget period
Fringe Benefits (\$)	Enter applicable fringe benefits, if any, for each senior/key person
Funds Requested (\$)	Enter federal funds requested for salary/wages & fringe benefits for each senior/key person for this budget period for this project.
Line 9. Total Funds Requested for all Senior Key Persons in the attached Files	Enter the total federal funds requested for all senior/key persons listed in the attached file (these requested funds would be for key persons over and above those listed in the preceding rows/fields of section A). If applicants are applying in hardcopy please attach a table listing the key personnel over and above the 8 persons listed on the budget page using the same format appearing in the budget table and enter the total funds requested for these additional by people in row 9.
Additional Senior Key Persons (attach file)	If applying electronically attach a file here detailing the funds requested for key personnel over and above the 8 senior/key persons already listed in this section; include all pertinent budget information. The total funds requested in this file should be entered in “ the total funds requested for all additional senior/key persons in line 9 of Section A. If applying in hardcopy please be certain to provide detailed information on the key personnel as well as funds requested in the same format appearing in the budget table. Be certain to include the total funds for these additional key persons in the total funds requested for all additional senior/key persons in line 9 of Section A.

SECTION B. Other Personnel

Field Name	Instructions
Number of Personnel	For each project role/category identify the number of personnel proposed.
Project Role	If project role is other than Post-Doctoral Associates, Graduate Students, Undergraduate students, or Secretarial/Clerical, enter the appropriate project role (for example, Engineer, Statistician, IT Professional etc.) in the blanks.
Cal. Months	Enter the number of Calendar months devoted to the project in the applicable box for each project role category/stipend category
Acad. Months	Enter the number of academic year months devoted to the project in the applicable box for each project role category (If your institute does not use a 9 month academic period , indicate your institution's definition of academic year in the budget justification)
Sum. Months	Enter the number of summer months devoted to the project in the applicable box for each project role category (If your institute does not use a 3 month summer period , indicate your institution's definition of summer period in the budget justification)
Requested Salary (\$)	Regardless of the number of months being devoted to the project, indicate only the amount of salary/wages/stipend amount being requested for each project role
Fringe Benefits (\$)	Enter applicable fringe benefits, if any, for each project role category
Funds Requested (\$)	Enter requested salary/wages & fringe benefits for each project role category
Total Number Other Personnel	Enter the total number of other personnel and related funds requested for this project
Total Salary, Wages and Fringe Benefits (A &B)	Enter the total funds requested for all senior key persons, stipends and all other personnel- If applying electronically this will be computed based on detailed information provided. If applying through hard copy please enter this number, ensuring that the total is equal to the detailed information provided

RESEARCH AND RELATED BUDGET

SECTION C, D, E,

Section C, D & E

SECTION C: Equipment Description

Field Name	Instructions
Organizational DUNS	Enter the DUNS or DUNS +4 number of your organization. For Project applicants and those applying electronically, this field is pre-populated from the R&R SF424 Cover Page.
Budget Type	Check the appropriate block. Check Project if the budget requested is for the primary applicant organization. Check Subaward/consortium organizations (if applicable). Separate budgets are usually required only for Subaward Budgets and are not allowed by HRSA unless legislatively authorized or requested in the program application guidance. Use the R&R Subaward Budget Attachment and attach as a separate file on the R&R Budget Attachment(s) form)
Enter Name of Organization	Enter the name of your organization
Start Date	Enter the requested Start Date of Budget Period
End Date	Enter the requested/proposed End Date of the Budget Period (these should cover 1 full year/12 months)
Budget Period	Identify the specific budget period (1 for first year of the grant, 2 for second year of the grant, 3 for third etc.)

Equipment Item	Equipment is identified as an item of property that has an acquisition cost of \$5,000 or more (unless the organization has established lower levels) and an expected service life of more than 1 year. List each item of equipment separately and justify each in the budget justification section. Ordinarily allowable items are limited to those which will be used primarily or exclusively in the actual conduct or performance of grant activities.
Funds Requested	Enter the estimated cost of each item of equipment, including shipping and any maintenance costs and agreements.
Total Funds Requested for all equipment listed in the attached files	Enter the estimated cost of all equipment listed in any attached documents/files.
Additional Equipment	If the space provided can not accommodate all the equipment proposed, attach a file or document delineating the equipment proposed. If applying in hardcopy please provide this information on a separate/attached sheet. List the total funds requested on line 11 of this section.

SECTION D. Travel

Field Name	Instructions
Domestic Travel Costs (Incl. Canada, Mexico, and US Possessions)	Enter the total funds requested for domestic travel. Domestic travel includes Canada, Mexico and US possessions. In the budget justifications section, include the purpose, destinations, dates of travel (if known), and number of individuals for each trip. If the dates of travel are known, specify estimated length of trip (for example, 3 days)
Foreign Travel Costs	Enter the total funds to be used for foreign travel. Foreign travel includes any travel outside of the United States, Canada, Mexico and or the U.S. Possessions. In the budget justification section, include the purpose, destination, travel dates (if known), and number of individuals for each trip. If the dates of travel are not known , specify estimated length of trip (ex. 3 days)
Total Travel Costs	The total funds requested for all travel related to this project– this should equal the total of all domestic and foreign and may be computed if applying electronically. If applying in hardcopy please enter this amount

RESEARCH AND RELATED BUDGET

SECTION C, D, E,

SECTION E: Participant/Trainee Support Costs

Field Name	Instructions
Tuition/Fees/Health Insurance	Enter the total amount of funds requested for participant /trainee tuition, fees, and /or health insurance. (if applicable)
Stipends	Enter the total amount of funds requested for participant /trainee stipends.
Travel	Enter the total funds requested for participant/trainee travel associated with this project (if applicable)
Subsistence	Enter the total funds requested for participant/trainee subsistence (if applicable)
Other	Describe and enter the total funds requested for any other participant/trainee costs/institutional allowances, scholarships etc. Please identify these in the space provided.
Number of Participants	Enter the total number of proposed participants/trainees (those receiving

	stipends, scholarships, etc.)
Trainee Costs	Enter the total costs associated with the above categories (i.e. participants/trainees- items 1-5). If applying electronically this total will be calculated for you.

RESEARCH AND RELATED BUDGET - SECTION F-K Budget Period

Field Name	Instructions
Organizational DUNS	Enter the DUNS or DUNS +4 number of your organization. For Project applicants and those applying electronically, this field is pre-populated from the R&R SF424 Cover Page.
Budget Type	Check the appropriate block. Check Project if the budget requested is for the primary applicant organization. Check Subaward/consortium organizations (if applicable). Separate budgets are usually required only for Subaward Budgets and are not allowed by HRSA unless legislatively authorized or requested in the program application guidance. Use the R&R Subaward Budget Attachment and attach as a separate file on the R&R Budget Attachment(s) form.
Enter Name of Organization	Enter the name of your organization
Start Date	Enter the requested Start Date of the Budget Period
End Date	Enter the requested/proposed End Date of the Budget Period (these should cover 1 full year/12 months)
Budget Period	Identify the specific budget period (1 for first year of the grant, 2 for second year of the grant, 3 for third etc.)

SECTION F. Other Direct Cost

Field Name	Instructions
1. Materials and Supplies	Enter the total funds requested for materials and supplies. In the budget justification attachment please itemize all categories for which costs exceed \$1,000. Categories less than \$1,000 do not have to be itemized.
2. Publication Costs	Enter the total publication funds requested. The budget may request funds for the cost of documenting, preparing, publishing or otherwise disseminating the findings of this project to others. In the budget justification include supporting information.
3. Consultant Services	Enter the total funds requested for consultant services. In the budget justification identify each consultant, the services to be performed, travel related to this project and the total estimated costs.
4. ADP/Computer Services	Enter total funds requested for ADP/computer services. In the budget justification include the established computer service rates at the proposed organization (if applicable)
5. Subawards/Consortia/ Contractual Costs	Enter total funds requested for subaward, consortium and/or contractual costs proposed for this project.
6. Equipment/Facility Rental/ User Fees	Enter total funds requested for equipment or facility rental or users fees. In the budget justification please identify and justify these fees.
7. Alterations and Renovations (not applicable to training program grants)	Enter the total funds requested for alterations and renovations. In the budget justification itemize by category and justify the costs including repairs, painting, removal or installation of partitions. Where applicable provide square footage and costs.
Items 8-10	In items 8-10 please describe any "other" direct costs not requested above. Use the Budget Justification attachment to

	further itemize and justify these costs. If line space is inadequate please use line 10 to combine all remaining “other direct costs” and include details of these costs in the budget justification.
Total Other Costs	The total funds requested for all Other Direct Costs

SECTION G: Direct Costs

If applying electronically, this item will be computed as the sum of sections A-F . If applying in paper please enter the sum of sections A-F in this field

SECTION H: Indirect Costs

Field Name	Instructions
Indirect Cost Type	Indicate the type of indirect cost. Also indicate if this is off-site. If more than one rate/base is involved, use separate lines for each. If you do not have a current indirect cost rate (s) approved by a Federal Agency indicate “None—will negotiate” and include information for proposed rate. Use the budget justification if additional space is needed.
Indirect Cost Rate (%)	Indicate the most recent indirect cost rate(s), also known as Facilities and Administrative Costs {F&A} established with a cognizant Federal office or, in the case of for-profit organizations, the rate(s) established with the appropriate agency. If you do not have a cognizant oversight agency and are selected for an award, you must submit your requested indirect cost rate documentation to the awarding department. For HHS this would be the Division of Cost Allocation in DHHS.
Indirect Cost Base (\$)	Enter amount of the base for each indirect cost type.
Funds Requested	Enter the total funds requested for each indirect cost type.
Cognizant Federal Agency	Enter the name of the cognizant Federal Agency, name and telephone number of the individual responsible for negotiating your rate. If no cognizant agency is known, enter None.

SECTION I: Total Direct and Indirect Institutional Costs (Section G+ Section H)

Enter the total funds requested for direct and indirect costs. If applying electronically this field will be calculated for you.

SECTION J: Fee

Generally, a fee is not allowed on a grant or cooperative agreement. Do not include a fee in your budget, unless the program announcement specifically allows the inclusion of a fee. If a fee is allowable, enter the fee requested in this field.

SECTION K: Budget Justification

Detailed instructions for information to include in this section will be provided in the program application guidance. Use the budget justification to provide the additional information in each budget category and any other information necessary to support your budget request. Please use this attachment/section to provide the information requested/required in the program guidance. Please refer to the guidance to determine the need for and placement of (ex. in Appendix section) any other required budget tables stipulated in the guidance.

RESEARCH AND RELATED BUDGET –CUMULATIVE BUDGET

If applying electronically, all of the values on this form will be calculated based on the amounts that were entered previously under sections A through K for each of the individual budget periods. Therefore, if this application is being submitted electronically no data entry is allowed or required in order to complete this Cumulative Budget section.

If any amounts displayed on this form appear to be incorrect you may correct the value by adjusting one or more of the values that contributed to the total from the previous sections. To make such an adjustment you will need to revisit the appropriate budget period form(s) to enter corrected values.

If applying in paper form please ensure that entries in the cumulative budget are consistent with those entered in Sections A-K.

Field Name	Instructions
Section A: Senior/Key Person	The cumulative total funds requested for all Senior/Key personnel.
Section B: Other Personnel	The cumulative total funds requested for all other personnel.
Total Number Other Personnel	The cumulative total number of other personnel.
Total Salary, Wages, and Fringe Benefits (Section A + Section B)	The cumulative total funds requested for all Senior/Key personnel and all other personnel.
Section C: Equipment	The cumulative total funds requested for all equipment.
Section D: Travel	The cumulative total funds requested for all travel.
1. Domestic	The cumulative total funds requested for all domestic travel.
2. Foreign	The cumulative total funds requested for all foreign travel.
Section E: Participant/Trainee Support Costs	The cumulative total funds requested for all participant/trainee costs.
1. Tuition/Fees/Health Insurance	Enter the number of Calendar months devoted to the project in the applicable box for each project role category.
2. Stipends	Enter the cumulative total funds requested for participants/trainee stipends.
3. Travel	The cumulative total funds requested for Trainee /Participant travel.
4. Subsistence	The cumulative total funds requested for Trainee/Participant subsistence.
5. Other	The cumulative total funds requested for any Other participant trainee costs including scholarships.
6. Number of participants/trainees	The cumulative total number of proposed participants/trainees.
Section F: Other Direct Costs	The cumulative total funds requested for all other direct costs.
1. Materials and Supplies	The cumulative total funds requested for Materials and Supplies.
2. Publication Costs	The cumulative total funds requested for Publications.
3. Consultant Services	The cumulative total funds requested for Consultant Services.
4. ADP/Computer Services	The cumulative total funds requested for ADP/Computer Services.
5. Subawards/ Consortium/ Contractual Costs	The cumulative total funds requested for 1) all subaward/ consortium organization(s) proposed for the project, and 2) any other contractual costs proposed for the project.
6. Equipment or Facility Rental/User Fees	The cumulative total funds requested for Equipment or Facility Rental/ User Fees.
7. Alterations and Renovations	The cumulative total funds requested for Alterations and Renovations.
8. Other 1	The cumulative total funds requested in line 8 or the first Other Direct Costs category.
9. Other 2	The cumulative total funds requested in line 9 or the second Other Direct Costs category.
10. Other 3	The cumulative total funds requested in line 10 or the third Other Direct Costs category.

Section G: Direct Costs A-F	The cumulative total funds requested for all direct costs.
Section H: Indirect Costs	The cumulative total funds requested for all indirect costs.
Section I : Total Direct and Indirect Costs	The cumulative total funds requested for direct and indirect costs.
Section J: Fee	The cumulative funds requested for Fees (if applicable).

INSTRUCTIONS FOR R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Subawards are not allowed by HRSA unless legislatively authorized or requested in the Program Application Guidance. Please click on the subaward budget attachment to obtain the required budget forms. Attach all budget information by attaching the files in line items 1-10. Please do not attach any files to the subaward documents as they will not be transferred to HRSA. All justification for expenditures should be added to the budget justification for the project in section K of the project budget.

SF 424 R&R ASSURANCES

Read the 424 R&R Assurances in the program guidance. Signing of the application FACE Page and sending the signed face page to the Grants Application Center (see guidance) indicates acceptance of these Assurances listed.

SF 424 R&R OTHER PROJECT INFORMATION COMPONENT

SF 424 R&R Other Project Information:

If this is an application for a Research Grant Please Respond to All of the Questions on this page.

If this is an application for a Training Grant Please Respond to Items 1 and Items 6-11.

Field Name	Instructions
1. Are Human Subjects Involved	If activities involving human subjects are planned at any time during proposed project check YES. Check this box even if the proposed project is exempt from Regulations for the protection of Human Subjects. Check NO if this is a training grant or if no activities involving human subjects are planned and skip to step 2.
1.a If YES to Human Subjects Involved	Skip this section if the answer to the previous question was NO. If the answer was YES, indicate if the IRB review is pending. If IRB has been approved enter the approval date. If exempt from IRB approval enter the exemption numbers corresponding to one or more of the exemption categories. See: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm for a list of the six categories of research that qualify for exemption from coverage by the regulations are defined in the Common Rule for the Protection of Human Subjects. For Human Subject Assurance Number enter the IRB approval number OR the approved Federal Wide Assurance (FWA) , multiple project assurance (MPA) , Single Project Assurance(SPA) Number or Cooperative Project Assurance Number that the applicant has on file with the Office of Human Research Protections, if available.
2. Are Vertebrate Animals Used	If activities using vertebrate animals are planned at any time during the proposed project at any performance site check the YES box; otherwise check NO and proceed to step 3.
2 a. If YES to	Indicate if the IACUC review is pending by checking YES in this field

Vertebrae animals	otherwise check NO. Enter the IACUC approval Date in the approval date field leave blank if approval is pending. For Animal Welfare Assurance Number , enter the Federally approved assurance number if available
3. Is Proprietary /Privileged Information Included in the Application	Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in the application only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, check the YES box and clearly mark each line or paragraph of the pages containing proprietary/privileged information with a legend similar to: “the following contains proprietary /privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation.
4a. Does this project have an actual or potential impact on the environment?	If your project will have an actual or potential impact on the environment check the YES box and explain in the box provided in 4b . Otherwise check NO and proceed to question 5a.
4.b. If yes, please explain	If you checked the YES box indicating an actual or potential impact on the environment, enter the explanation or the actual or potential impact on the environment here.
4c. If this project has an actual or potential impact on the environment has an exemption been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed?	If an exemption has been authorized or an EA or EIS has been performed check the YES box in 4d. Otherwise check the NO box.
4d. If yes please explain	If you checked the YES box indicating an exemption has been authorized or an EA or EIS has been performed, enter the explanation.
5a. Does the project involve activities outside of the U.S. or partnership with international collaborators?	If your project involves activities outside of the U.S. or partnerships with international collaborators check the YES box and list the countries in the box provided in 5b and an optional explanation in box 5c. Otherwise check NO and proceed to item 6.
5b. If yes Identify Countries	If the answer to 5a is YES – identify the countries with which international cooperative activities are involved.
5c. Optional explanation	Use this box to provide any supplemental information, if necessary. If necessary you can provide the information as an attachment by clicking “Add Attachment” to the right of Item 11 below.
6. Project Summary/ Abstract	Please refer to the guidance for instructions regarding the information to include in the project summary/abstract. The project summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of the objectives and methods employed. The summary must NOT include any proprietary/confidential information. If applying electronically attach the summary/abstract by clicking on “Add Attachment” and browse to where you saved the file on your computer and attach.
7. Project Narrative	Provide the project narrative in accordance with the program

	guidance/announcement and/or agency/program specific instructions. If you are applying electronically, to attach project narrative click “Add Attachment,” browse to where you saved the file, select the file, and click to attach. .
8. Bibliography and References Cited	Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers and year of publication. Include only bibliographic citations. Be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of this application. If applying electronically – attach the bibliography by clicking “Add Attachment” on line 8.
9. Facilities and Other Resources	This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their pertinent capabilities, relative proximity and extent of availability to the project (e.g. machine shop, electronic shop), and the extent to which they would be available to the project. To attach a Facilities and Other Resources file, click Add Attachment, browse to where you saved the file, select the file and then click open.
10. Equipment	List major items of equipment already available for this project and if appropriate identify location pertinent capabilities. To attach an Equipment file click “Add Attachment “ and select the file to be attached.
11. Other Attachments	Attach a file to provide any program specific forms or requirements not provided elsewhere in the application in accordance with the agency or program specific guidance. Click “Add Attachment” and select the file for attachment from where you saved the file.

ATTACHMENTS FORM

Use this form to add files/attachments required in the program guidance whose location has not been specified elsewhere in the application package. Use the first line item to attach the file with information on your organization’s Business Official. Name this file BUSINESS OFFICIAL INFORMATION. Attach other files as required in the program guidance.

