

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Health Resources and Services Administration**

Healthcare Systems Bureau

Division of Transplantation

**Clinical Interventions for Increasing Organ Procurement  
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Catalog of Federal Domestic Assistance (CFDA) No. 93.134**

**PROGRAM GUIDANCE**

**Fiscal Year 2007**

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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

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.

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

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](mailto: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.

## 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
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 <b>PureEdge</b> 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.	<b>Required</b>
Facilities & Other Resources	Attachment	Can be uploaded in Other Project Information form, Box 9.	<b>Required</b>
Equipment	Attachment	Can be uploaded in Other Project Information form, Box 10.	<b>Required if appropriate for the project.</b>
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 <b>specific</b> 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.

**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/dunsccr.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

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.

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

[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

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**

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](http://www.grants.gov). Assistance also is available from the NIH Grants.gov help desk at [support@grants.gov](mailto: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.

- 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

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](http://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](http://www.hhs.gov/ohrp/assurances/assurances_index.html) or by emailing inquiries to [ohrp@osophs.dhhs.gov](mailto: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](http://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;

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](mailto: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](mailto:jperdue@hrsa.gov)

## **VIII. Other Information**

### **A. Internet Resources**

Applicants are encouraged to refer to DoT's web site, [www.organdonor.gov](http://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](http://www.organdonor.gov). Further information may be obtained by contacting Ms. Jade Perdue at [jperdue@hrsa.gov](mailto: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

## 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](http://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.

# 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)

## 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](mailto: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>).

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](mailto: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](mailto: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.

## **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.**

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 1/2" 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.

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](mailto: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.

## **6.2 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

## 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 [DGPCclearances@hrsa.gov](mailto:DGPCclearances@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](http://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)

## 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

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.

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

## 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.
Street 1	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

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 <b>Prefix, First/(Given) name, Middle name</b> (if applicable), <b>Last Name</b> and <b>Suffix</b> 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 <b>"the total funds requested for all additional senior/key persons in line 9 of Section A.</b> 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 <b>the total funds requested for all additional senior/key persons in line 9 of Section A.</b>

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

	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.

<b>Section G: Direct Costs A-F</b>	The cumulative total funds requested for all direct costs.
<b>Section H: Indirect Costs</b>	The cumulative total funds requested for all indirect costs.
<b>Section I: Total Direct and Indirect Costs</b>	The cumulative total funds requested for direct and indirect costs.
<b>Section J: Fee</b>	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: <a href="http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm">http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm</a> 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

	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.