SF-424 R&R Application Guide

A guide developed and maintained by HRSA for preparing and submitting applications through Grants.gov to HRSA using the SF-424 R&R Application Package

To be used with HRSA funding opportunity announcements (FOAs) specifying the use of the SF-424 R&R Application Package

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1. INTRODUCTION

1.1. About HRSA

HRSA's mission is to improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs. HRSA provides access to essential health care services for people who are low-income, uninsured, or live in rural areas or urban neighborhoods where access to or availability of health care is limited. HRSA provides leadership and financial support to health care providers in every state and U.S. territory. HRSA-funded health centers provide medical care to more than 20 million patients each year at more than 8,500 sites nationwide. HRSA awardees provide health care to uninsured people, people living with HIV/AIDS, and pregnant women, mothers and children. They train health professionals and improve systems of care in rural communities.

HRSA oversees organ, bone marrow and cord blood donation. It supports programs that compensate individuals harmed by vaccination and maintains databases that protect against health care malpractice and health care waste, fraud and abuse. For more information please visit our website at http://www.hrsa.gov.

1.2. Document Purpose and Scope

The purpose of this document is to provide detailed instructions to help you (the applicant organization/agency), prepare and submit new, competing continuation, and competing supplement applications electronically to HRSA through Grants.gov. This *SF-424 R&R Application Guide* is specific to funding opportunity announcements (FOAs) using the Application for Federal Assistance SF-424 Research and Related (R&R) application package**** for research or training awards. You must submit electronically through Grants.gov**. This *Guide* is intended to be a concise source of HRSA general information related to the application preparation and submission process and will be updated periodically. This document does not replace program-specific guidance provided in FOAs. This document also does not replace the Health and Human Services Grants Policy Statement (HHS GPS), which serves as the comprehensive source of grant information across the Department.

Note: As of October 1, 2010 current awardees are no longer required to submit a full application to determine eligibility for funding of a successive budget period within their approved project period. Instead, awardees only need to submit the streamlined Non-Competing Continuation (NCC) Progress Report for continued funding of the next budget period. For details and user guides, please visit http://www.hrsa.gov/grants/noncompetingcontinuations/index.html.

**If you are applying for awards that require the SF-424 Non-Construction application package, you must refer to HRSA's *SF-424 Application Guide* at http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf for guidance.

1.3. Document Version Control

This document is periodically updated and maintained by HRSA's Office of Federal Assistance Management, Division of Grants Policy.

1.4. Summary of Significant Changes

5/26/16:

- Mandatory Disclosures details/contact information added in Section 2.2. Administrative and National Policy Requirements.
- National HIV/AIDS Strategy (NHAS) section updated (includes pre-exposure prophylaxis (PrEP) and HIV Care Continuum information) in Section 2.2. Administrative and National Policy Requirements.
- Funding Restrictions section updated with a listing of legislative mandates in Section 4.1.iv. Budget.

2/5/16:

- All references/information related to P.L. 113-235 updated to P.L. 114-113, the Consolidated Appropriations Act, 2016.
- "Cultural and Linguistic Competence" language updated in Section 2.2. Administrative and National Policy Requirements.
- Salary Limitation information/amounts updated in Sections 4.1.*iv. Budget* and *v. Budget Justification Narrative (Personnel Costs)*.
- Directions updated and clarifications added regarding biographical sketches in Section 4.1.*vi. Staffing Plan and Personnel Requirements* and Appendix A.
- Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification added to Section 4.1.*viii. Certifications*.

8/10/15: The "Non-Discrimination Requirements" section has been enhanced and renamed "Accessibility Provisions and Non-Discrimination Requirements."

5/14/15: Various updates/requirements per the Uniform Guidance including: Mandatory Disclosure, Classification of Costs.

2. POLICIES, ASSURANCES, DEFINITIONS AND OTHER INFORMATION

2.1. HHS Grants Policy Statement

HRSA grant and cooperative agreement awards are subject to the requirements of the HHS GPS that are applicable based on recipient type and purpose of award. This includes any requirements in Parts I and II of the HHS GPS that apply to the award. The HHS GPS is available at http://www.hrsa.gov/grants/hhsgrantspolicy.pdf. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in the Notice of Award (NoA)).

2.2. Administrative and National Policy Requirements

Effective December 26, 2014, all administrative and audit requirements and the cost principles that govern federal monies associated with an application and award will be subject to the Uniform Guidance 2 CFR part 200 as codified by HHS at 45 CFR part 75, which supersede the previous administrative and audit requirements and cost principles.

Successful applicants are required to comply with the administrative requirements outlined in 45 CFR part 75 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.

In addition to the numerous administrative and national policy requirements imposed by regulation and by the HHS GPS, HRSA stresses the following terms of every award:

Accessibility Provisions and Non-Discrimination Requirements
Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see http://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html; and http://www.hhs.gov/civil-rights/for-providers/index.html. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html. Please contact the HHS Office for Civil Rights for more information about obligations and

prohibitions under federal civil rights laws at http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

Acknowledgement of Federal Funding

HRSA requires recipients to use the following acknowledgement and disclaimer on all products produced by HRSA funds:

> "This project is/was supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number and title for grant amount (specify grant number, title, total award amount and percentage financed with nongovernmental sources). This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government."

Recipients are required to use this language when issuing statements, press releases, requests for proposals, bid solicitations, and other HRSA-supported publications and forums describing projects or programs funded in whole or in part with HRSA funding. Examples of HRSA-supported publications include, but are not limited to, manuals, toolkits, resource guides, case studies and issues briefs.

Affordable Care Act Outreach and Education

It is important to note that a healthier country is one in which more Americans are able to access the care they need to prevent the onset of disease and manage disease when it is present. Insurance coverage is strongly related to better health outcomes for both children and adults. Access to insurance improves health outcomes by helping people obtain preventive and screening services, prescription drug benefits, mental health and other services, and by improving continuity of care.

The Affordable Care Act , the health care law of 2010, creates new state-based marketplaces, also known as exchanges, to offer millions of Americans new access to affordable health insurance coverage. Individuals with incomes between 100 to 400 percent FPL may be eligible to receive advance payments of premium tax credits and/or cost-sharing reductions to help pay for the cost of enrolling in a qualified health insurance plan and paying for coverage of essential health benefits. In states that choose to participate in the Affordable Care Act expansion of Medicaid to non-disabled adults with incomes of up to 133 percent of Federal Poverty Level (FPL), this provision will provide new coverage options for many individuals who were previously ineligible for Medicaid. In addition, the law helps make prevention affordable and accessible for Americans by requiring health plans to cover certain recommended preventive services without cost sharing.

Outreach efforts would ensure that families and communities understand these new developments and would provide eligible individuals the assistance they need to secure and retain coverage as smoothly as possible during the transition and beyond. You are encouraged to share information with your beneficiaries about these options and to assist them, to the extent it is an appropriate activity under your award, in enrolling in available insurance plans or in finding other available sources of payment for the services you provide.

To learn more about the Health Insurance Marketplace and enroll in coverage, visit HealthCare.gov. Awardees should direct individuals, families, and partners to HealthCare.gov to access educational information and create accounts, complete an online application, shop for qualified health plans, and enroll in coverage. The site is also available in Spanish at CuidadoSalud.gov (https://www.cuidadodesalud.gov/es/).

A wide range of enrollment and education assistance is available. Individuals can go to https://localhelp.healthcare.gov to find a trained in-person assistor in their community, use the live chat function on HealthCare.gov, or contact the Health Insurance Marketplace call center toll free at 1-800-318-2596 (TTY 1-855-889-4325), which is available 24/7 in 150 languages.

For more information on the marketplaces and the health care law, visit http://www.healthcare.gov/. In addition, for professionals learning about the Marketplace and helping people apply, get the latest resources at http://marketplace.cms.gov/.

Cultural and Linguistic Competence

HRSA programs serve culturally and linguistically diverse communities that are not just defined by race or ethnicity, but also socio-economic status, sexual orientation, gender identity, physical and mental ability, age, and other factors. Organizational behaviors, practices, attitudes, and policies across all HRSA-supported entities respect and respond to the cultural diversity of communities, clients and students served.

HRSA is committed to ensuring access to quality health care for all. Quality care means access to services, information, and materials delivered by competent providers in a manner that factors in the language needs, health literacy, culture, and diversity of the populations served. Quality also means that data collection instruments used should adhere to culturally competent and linguistically appropriate norms. For additional information and guidance, refer to the National Standards for Culturally and Linguistically Appropriate Services (CLAS) published by the U.S. Department of Health and Human Services at https://www.thinkculturalhealth.hhs.gov/. Additional cultural/linguistic competency and health literacy tools, resources and definitions are available online at http://www.hrsa.gov/culturalcompetence and http://www.hrsa.gov/healthliteracy.

DOMA: Implementation of United States v. Windsor and Federal Recognition of Same-Sex Spouses/Marriages

References: United States v. Windsor, 133 S.Ct. 2675 (June 26, 2013); § 3 of the Defense of Marriage Act, codified at 1 USC § 7.

The following applies to **all HRSA grant programs except:**

- block grants governed by 45 CFR part 96,
- block grants governed by 45 CFR part 98, and
- grant awards made under titles IV-A, XIX and XXI of the Social Security Act.

A standard term and condition of award will be included in the NoA that states: "In any grant-related activity in which family, marital, or household considerations are, by statute or regulation, relevant for purposes of determining beneficiary eligibility or participation, grantees must treat same-sex spouses, marriages, and households on the same terms as opposite-sex spouses, marriages, and households, respectively. By "same-sex spouses," HHS means individuals of the same sex who have entered into marriages that are valid in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. By "same-sex marriages," HHS means marriages between two individuals validly entered into in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. By "marriage," HHS does not mean registered domestic partnerships, civil unions or similar formal relationships recognized under the law of the jurisdiction of celebration as something other than a marriage."

Financial Conflict of Interest

HHS requires awardees and investigators to comply with the requirements of 42 CFR part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." A Final Rule amending this PHS regulation (and the companion regulation at 45 CFR part 94, "Responsible Prospective Contractors," imposing similar requirements for research contracts) was published on August 25, 2011 in the Federal Register (http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf). An Institution applying for or receiving PHS funding from a grant or cooperative agreement that is covered by the rule must be in full compliance with all of the revised regulatory requirements no later than August 24, 2012, and immediately upon making its institutional Financial Conflict of Interest (FCOI) policy publicly accessible as described in the regulation.

Health IT
Health information technology (Health IT) provides the basis for improving the overall quality, safety and efficiency of the health delivery system. HRSA endorses the widespread and consistent use of health IT, which is the most promising tool for making health care services more accessible, efficient and cost effective for all Americans.

Related Health IT Resources:

- Health Information Technology (HHS): http://www.healthit.gov/
- What is Health Care Quality and Who Decides? (AHRQ): http://www.ahrq.gov

Healthy People 2020
Healthy People 2020 is a national initiative led by HHS that sets priorities for all HRSA programs. The initiative has four overarching goals: (1) attain high-quality, longer lives free of preventable disease, disability, injury, and premature death; (2) achieve health equity, eliminate disparities, and improve the health of all groups; (3) create social and physical environments that promote good health for all; and (4) promote quality of life, healthy development, and healthy behaviors across all life stages. The program consists of over 40 topic areas, containing measurable objectives. HRSA has actively participated in the work groups of all the topic areas and is committed to the achievement of the Healthy People 2020 goals. More information about Healthy People 2020 may be found online at http://www.healthypeople.gov/.

Human Subjects Protection
Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, awardees must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR 46), available online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.
NOTE: Please see Appendix B of this *SF-424 R&R Application Guide* for supplemental instructions for preparing the human subjects section of the research plan.

Integrating Primary Care and Public Health
Integration of primary care and public health links people, policy, programs and activities to increase efficiency and effectiveness and ultimately improve population health. Both primary care and public health emphasize prevention as a key driver of better health, and integration of the two fields can transform our focus on disease and treatment to health and wellness, as well as maximize our health care system investment. Integration occurs on a continuum and includes mutual awareness, cooperation, collaboration and partnership. Successful integration requires primary care and public health to work together along this continuum and address social and

environmental determinants of health, engage communities, align leadership, develop the healthcare workforce, sustain systems, and share and collaborate on the use of data and analysis – all with an eye toward achieving a shared goal of population health improvement. Integration of primary care and public health is a major focus for HRSA and HHS, and to the extent possible, you should consider ways to integrate primary care and public health in the activities they pursue. More information can be found at http://www.hrsa.gov/publichealth/.

Mandatory Disclosures

The non-federal entity or applicant for a federal award must disclose, in a timely manner, in writing to the HHS awarding agency or pass-through entity all violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award (45 CFR § 75.113). Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).

Submission is required for all applicants and recipients, in writing, to the awarding agency and to the HHS Office of Inspector General (OIG) all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to:

HRSA (The Awarding Agency)

AND

U.S. Department of Health and Human Services
Office of Inspector General
ATTN: Mandatory Grant Disclosures, Intake Coordinator
330 Independence Avenue, SW, Cohen Building
Room 5527
Washington, DC 20201
URL: http://oig.hhs.gov/fraud/report-fraud/index.asp
(Include "Mandatory Grant Disclosures" in subject line)
Fax: (202) 205-0604 (Include "Mandatory Grant Disclosures" in subject line) or
E-mail: MandatoryGranteeDisclosures@oig.hhs.gov

National HIV/AIDS Strategy (NHAS): Updated to 2020

The National HIV/AIDS Strategy for the United States: Updated to 2020 (NHAS 2020 or Strategy) is a five-year plan that details principles, priorities, and actions to guide the national response to the HIV epidemic. To the extent possible, program activities should strive to support the primary goals of NHAS 2020:

- Reduce new HIV infections;
- Increase access to care and optimize health outcomes for people living with HIV (PLWH);

- Reduce HIV-related health disparities and health inequities; and
- Achieve a more coordinated national response to the HIV epidemic.

Updated in 2015, NHAS 2020 has fully integrated the objectives and recommendations of the HIV Care Continuum Initiative (see below) and the Federal Interagency Working Group on the Intersection of HIV/AIDS, Violence against Women and Girls, and Gender-Related Health Disparities. The Strategy also allows opportunities to refocus and strengthen the ongoing work in HIV prevention, care, and research.

Recipients should take action to align their organization's efforts, over the next five years, around the Strategy's four areas of critical focus:

- Widespread testing and linkage to care, enabling PLWH to access treatment early;
- Broad support for PLWH to remain engaged in comprehensive care, including support for treatment adherence;
- Universal viral suppression among PLWH; and
- Full access to comprehensive pre-exposure prophylaxis (PrEP) services for those to whom it is appropriate and desired, and support for medication adherence for those using PrEP.

More information on how recipients can support NHAS 2020, including the Community Action Plan Framework, a tool to help recipients and other stakeholders in developing their own plans to implement NHAS 2020, can be found here: https://aids.gov/federal-resources/national-hiv-aids-strategy/overview/.

HIV Care Continuum

The HIV care continuum includes the diagnosis of HIV, linkage to HIV medical care, lifelong retention in HIV medical care, appropriate prescription of ART, and, ultimately, HIV viral load suppression. The HIV care continuum performance measures align with the [U.S. Department of Health and Human Services] HHS Common HIV Core Indicators, approved by the HHS Secretary. RWHAP recipients and providers submit data through the RSR. HAB collects the data elements needed to produce the HHS Common HIV Core Indicators (Indicators); uses the data to calculate Indicators, across the entire RWHAP; and reports six of the seven Indicators to the HHS, Office of the Assistant Secretary for Health.

RWHAP recipients are encouraged to assess the outcomes of their programs along the HIV care continuum and work with their community and public health partners to improve outcomes, so that individuals diagnosed with HIV are linked to and engaged in care and started on ART as early as possible. HAB requests that recipients use the RWHAP performance measures, at their local level, to assess the efficacy of their programs and to analyze and improve the gaps along the HIV care continuum.

Pilot Program for Enhancement of Contractor Employee Whistleblower Protections

Awards issued under HRSA FOAs are subject to the requirements of 48 CFR § 3.908. A standard term and condition of award requires that grantees inform their employees in writing of employee whistleblower rights and protections under 41 U.S.C. 4712 in the predominant native language of the workforce. (Regarding 48 CFR § 3.908, note that use of the term "contract," "contractor," "subcontract," or "subcontractor" for the purpose of this term and condition, should read as "grant," "grantee," "subgrant," or "subgrantee.")

Research Misconduct

The recipient is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. The recipient will inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent research misconduct. 42 CFR part 93, "Public Health Service Policies on Research Misconduct," specifies recipient responsibilities for dealing with and reporting possible research misconduct. The regulation is available from the Office of Research Integrity (ORI) on its home page (http://www.ori.dhhs.gov).

The recipient must carry out its responsibilities with extra care if a research misconduct inquiry has been initiated as specified in 42 CFR § 93.307 or if the recipient or ORI has made a finding of research misconduct. The recipient must report promptly to ORI any incident of alleged or apparent research misconduct that it judges as warranting investigation and must advise ORI of any decision to initiate an investigation. The recipient also must notify ORI if it intends to close a case at the inquiry or investigation stage based on an admission of responsibility, settlement, or for any other reason. The regulations also require that the recipient submit an annual report.

If a misconduct investigation has been initiated, the recipient must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project, protect human subjects and animals, provide reports to ORI, and ensure the proper expenditure of funds and continuation of the project during the investigation, if appropriate. ORI staff members are available to help recipients with investigating and reporting on research misconduct, and POs are available to provide technical assistance and to work with recipients to protect funded projects from the adverse effects of research misconduct.

If the recipient finds research misconduct by anyone working on an HHS grant-supported project, whether at its organization or at a third-party organization, the recipient must assess the effect of that finding on the ability to continue that project, as originally approved, and must promptly request OPDIV prior approval of any intended change of PI or other key personnel (see "Prior Approval Requirements—OPDIV Prior Approval" in the HHS GPS). In addition, the awarding office may impose sanctions, such as withdrawal of approval of the PI/PD or other key personnel, disallowance of costs associated with the invalid or unreliable research, withholding a non-competing

continuation award, suspension or termination, in whole or in part, of the current award, or debarment.

If research misconduct has affected data validity or reliability, ORI or the OPDIV may require the recipient and its employee/collaborator authors to submit a correction or retraction of the data to a journal, publish the corrected data, or both. If the recipient does not comply with this requirement, the OPDIV may invoke its rights, under 45 CFR part 74 or 92, to access the data (including copyrightable material developed under the award), have the data reviewed, and submit the correction.

The recipient must promptly report issues involving potential civil or criminal fraud, such as false claims or misappropriation of federal funds, to the HHS OIG.

Smoke-Free Workplace
The Public Health Service strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. Further, Public Law (P.L.) 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

Standards for Financial Management
Recipients are required to meet the standards and requirements for financial management systems set forth in 45 CFR part 75. The financial systems must enable the recipient to maintain records that adequately identify the sources of funds for federally assisted activities and the purposes for which the award was used, including authorizations, obligations, unobligated balances, assets, liabilities, outlays or expenditures, and any program income. The system must also enable the recipient to compare actual expenditures or outlays with the approved budget for the award.

HRSA funds must retain their award-specific identity—they may not be commingled with state funds or other federal funds. ["Commingling funds" typically means depositing or recording funds in a general account without the ability to identify each specific source of funds for any expenditure.]

Trafficking in Persons
Awards issued under HRSA FOAs are subject to the requirements of Section 106(g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104). For the full text of the award term, go to http://www.hrsa.gov/grants/trafficking.html.

NOTE: The signature of the AOR (by checking "I agree" in Box 17 of SF-424 R&R) on the application serves as the required certification of compliance for your organization regarding the administrative and national policy requirements.

2.3. Compliance Requirements at a Glance

For reference, the chart below provides compliance requirements by recipient and requirement type.

Compliance Requirements at a Glance			
Recipient Type	**Administrative Requirements**	**Cost Principles**	**Audit Requirements**
State, Local, & Tribal Governments	45 CFR part 75	45 CFR 75; Subpart E	45 CFR 75; Subpart F
Colleges & Universities			
Non-Profits			
Hospitals		45 CFR part 75, Appendix IX	
For-Profits		48 CFR Subpart 31.2 (FAR 31.2)	
Foreign		As stated above for each awardee type	45 CFR part 75 except where the HHS awarding agency determines that the application of these subparts would be inconsistent with the international obligations of the United States or the statutes or regulations of a foreign government.

2.4. Assurances and Certifications

Complete Application Form SF-424B Assurances – Non-Construction Programs.

The signature of the AOR (by checking “I agree” in Box 17 of SF-424 R&R) on the application serves as the required certification of compliance for the applicant organization regarding Lobbying. See Section 4.1.viii of this *SF-424 R&R Application*

Guide for more details. If applicable, complete the Standard Form-LLL Disclosure of Lobbying Activities Form provided with the application package.

2.5. References

About HRSA
http://www.hrsa.gov/about/index.html

Grants.gov Online User Guide
http://www.grants.gov/help/html/help/index.htm?callingApp=custom#t=Get_Started%2FGet_Started.htm

How to Apply for a Grant
http://www.hrsa.gov/grants/apply/index.html

Tips for Preparing Grant Proposals
http://www.hhs.gov/asfr/ogapa/aboutog/apptips.html

System for Award Management (SAM)
https://www.sam.gov

2.6. Definitions

Term	Definition
508 Compliant	Section 508 of the Rehabilitation Act (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 (P.L. 105-220), August 7, 1998 requires that all Web site content be equally accessible to people with disabilities. This applies to Web applications, Web pages and all attached files. It applies to intranet as well as public-facing Web pages. For more information, visit: http://www.hrsa.gov/about/508Resources.html.
Administrative Requirements	The general practices that are common to the administration of federal awards, such as financial accountability, reporting, equipment management, and retention of records.
Allocable Cost	A cost that is allocable to a particular cost objective (i.e., a specific function, grant/cooperative agreement project, service, department, or other activity) in accordance with the relative benefits received. A cost is allocable to a federal award where it is treated consistently with other costs incurred for the same purpose in like circumstances and (1) is incurred specifically for the award, (2) benefits both the award and other work and can be distributed in reasonable proportion to the benefits received, and (3) is necessary for the overall operation of the organization.

Allowable Cost	A cost incurred by a recipient that is reasonable for the performance of the award; allocable; in conformance with any limitations or exclusions set forth in the federal cost principles applicable to the organization incurring the cost or in the NoA as to the type or amount of cost; consistent with regulations, policies, and procedures of the recipient that are applied uniformly to both federally supported and other activities of the organization; accorded consistent treatment as a direct or indirect cost; determined in accordance with generally accepted accounting principles; and not included as a cost in any other federally supported award (unless specifically authorized by statute).
Assurance	A written statement by an applicant, normally included with the application, indicating that it will abide by a particular requirement if an award is made.
Authorized Organization Representative (AOR)	An AOR is a role in Grants.gov. AORs are the individuals named by the applicant/recipient organization, who are authorized to act for the applicant/recipient and to assume the obligations imposed by the federal laws, regulations, requirements, and conditions that apply to applications or awards. AORs are approved by the organization's E-Business Point of Contact and are authorized and designated to submit applications through Grants.gov on behalf of an organization.
Authorizing Official (AO)	An Authorizing Official is a role in the HRSA Electronic Handbooks (EHBs). In the event that an application or portion of an application is to be submitted through the EHBs (IF indicated in the FOA), this individual is responsible for certifying and submitting it to HRSA.
Award	The document that provides HRSA funds to a recipient to carry out an approved program or project (based on an approved application or progress report). The term, when used as a noun, is sometimes used interchangeably with "grant" or "cooperative agreement."
Budget Periods	The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes. Funding of individual budget periods sometimes is referred to as "incremental funding."
Chief Grants Management Officer (CGMO)	The CGMO is HRSA's representative on federal award policy directives and award administration matters.

Competing Continuation Application	A request for funding to renew, by one or more additional budget periods (described as a "competitive segment"), a project period that would otherwise expire. This type of application is sometimes referred to as "renewal." These applications must compete for support in the same manner as new applications. ("Type 2" award)
Competing Supplement Application	A request in response to an FOA for an increase in support in a current budget period for expansion of the scope of the approved project or program. ("Type 3" award)
Consumer/Provider Board Participation	Allowable costs in accordance with applicable program regulations. When not specifically authorized by program regulations, only the following costs are allowable with OPDIV prior approval: • Reasonable and actual out-of-pocket costs incurred solely as a result of attending a scheduled meeting, including transportation, meals, babysitting fees, and lost wages. • The reasonable costs of necessary meals furnished by the recipient to consumer or provider participants during scheduled meetings if not reimbursed to participants as per diem or otherwise. Where programmatic regulations permit such payments but establish a maximum annual income for eligibility for reimbursement of consumer/provider board members for wages lost by reason of their participation in board activities, the determination of eligibility will be made on the basis of gross rather than net income. Members of consumer/provider boards are not considered employees or consultants of the recipient. Therefore, they may not be compensated for their services other than as above, nor are they eligible for associated fringe benefits. Although not eligible for individual insurance coverage, board members may be covered by an organizational insurance policy while acting in their official capacities as board members.
Cooperative Agreement	A legal instrument of financial assistance used when there will be substantial federal programmatic involvement. Substantial involvement means that HRSA program staff will collaborate or participate in project or program activities as specified in the FOA and NoA. See full definition at 45 CFR § 75.2 Definitions.
Cost Principles	The government-wide principles, issued by OMB (or, in the case of commercial organizations, the Federal Acquisition Regulation, or in the case of hospitals, 45 CFR part 75, Appendix IX, "Principles For Determining Costs Applicable to Research and Development Under Grants and Contracts With Hospitals"), on

	allowability and unallowability of costs under federally sponsored agreements.
Cost Sharing	The portion of project costs not paid by federal funds (unless otherwise authorized by federal statute). This may include the value of allowable third party in-kind contributions, as well as expenditures by the recipient. Costs used to satisfy matching or cost-sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.
DUNS Number	Data Universal Numbering System (DUNS) number, is a nine-digit number established and assigned by Dun and Bradstreet to currently uniquely identify a business entity. This number is also known as the Unique Entity Identifier.
Equipment	An article of tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-federal entity for financial statement purposes, or $5,000.
Executive Order 12372 (Intergovernmental Review of Federal Programs)	The source of the requirement that state and local officials review certain proposed federal financial assistance. For those states that participate in the process, a single state official or organization is designated for coordination of the review process and to send official state process comments and recommendations to federal agencies. These state officials or organizations are referred to as State Single Points of Contact. (45 CFR part 100, "Intergovernmental Review of Department of Health and Human Services Programs and Activities," is the HHS implementation of the Executive order.)
Federal Award Identification Number (FAIN)	The FAIN is a unique number assigned to each federal award by the awarding agency (aka "grant number" it's the 10-digit number found in box 4b of the NoA). This number is used on all award documents. Pass-through entitites are required to inform subrecipients of this number and associated requirements of use.
Funding Opportunity Announcement (FOA)	HRSA's formally issued announcement of the availability of federal funding through one of its financial assistance programs. The announcement invites applications and provides such information as eligibility and evaluation criteria, funding preferences/priorities, how to obtain application packages, and the submission deadline.
Funding Preference	The funding of a specific category or group of applications ahead of other categories or groups of applications that are recommended for approval. Applicants that meet the criteria for the preference will be placed in a more competitive position among applications that can be funded. Applications that do not

	receive a funding preference will be given full and equitable consideration during the review process.
Funding Priority	The favorable adjustment of combined review scores of individually approved applications when applications meet specified criteria. An adjustment is made by a set, pre-determined number of points.
Funding Special Consideration	A special consideration is defined as the favorable consideration of an application by HRSA funding officials, based on the extent to which the application addresses the specific area of special consideration.
Grant	A legal instrument of financial assistance between a federal awarding agency or pass-through entity and a non-federal entity that, consistent with 31 U.S.C. 6302, 6304, is used to enter into a relationship the principal purpose of which is to transfer anything of value from the federal awarding agency or pass-through entity to the non-federal entity to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the federal awarding agency or pass-through entity's direct benefit or use. A grant is used whenever HRSA anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities. See full definition at 45 CFR § 75.2 Definitions.
Grants Management Officer (GMO)	The GMO is the official whose name appears on the NoA and is the individual designated to serve as the HHS official responsible for the business and non-programmatic management aspects of a particular grant(s) or cooperative agreement(s). In this capacity, the GMO is responsible for all federal business management matters associated with the review, negotiation, award, and administration of the assigned grants/cooperative agreements and interprets federal award administration policies and provisions. The Grants Management Officer also serves as the counterpart to the business officer of the recipient organization. The GMO is the only official authorized to obligate HRSA to the expenditure of federal funds or to change the funding, duration, or other terms and conditions of an award.
Grants Management Specialist (GMS)	The GMS works with the GMO on the day-to-day business and nonprogrammatic management of a portfolio of HRSA grants and cooperative agreements. The GMS performs many of the activities described above on behalf of the GMO and is usually the primary point of contact for recipients when dealing with award-related issues. He/she also works closely with the federal project

	officer (PO) or program official aka program contact.
Indirect Cost Rate	The rate negotiated by the cognizant federal agency that is used as the basis for reimbursing indirect costs. The rate may be applicable to an entire organization, on-site activities or off-site activities only, a particular site, or specified activities. The rate must be effective for the period for which reimbursement is claimed. Rates may be fixed, predetermined, provisional, or final, consistent with the applicable federal cost principles.
Indirect Cost Rate Agreement	The document that formalizes the establishment of an indirect cost rate(s) and provides information on the proper application of the rate(s).
Indirect Costs	Costs incurred for common or joint objectives which cannot be readily and specifically identified with a particular project or program but are necessary to the operations of the organization, e.g., the cost of operating and maintaining facilities, depreciation, and administrative salaries. For some institutions, the term "facilities and administration" (F&A) is used to denote indirect costs. **Reminder**: Indirect costs should be calculated within the total requested costs.
Institutional Review Board (IRB)	An Institutional Review Board is a committee that performs ethical review of proposed research.
Key Personnel	Per the HHS GPS, the PI/PD and other individuals who contribute to the programmatic development or execution of a project or program in a substantive, measurable way, whether or not they receive salaries or compensation under the grant.
Letter of Intent	A preliminary, non-binding indication of an organization's intent to submit an application.
Local Government	Any unit of government within a state, including a county, borough, municipality, city, town, township, parish, local public authority (including any public housing agency under the United States Housing Act of 1937), school district, special district, intrastate district, council of governments (whether or not incorporated as a nonprofit corporation under state law), and any other agency or instrumentality of a multi-, regional, or intra-state or local government. The term does not include institutions of higher education and hospitals.
Matching	See Cost Sharing.
Maintenance of Effort	A requirement contained in the authorizing statute or program regulations stating that, in order to receive federal funds, a recipient must agree to maintain a specified level of financial effort (using a specified baseline period, such as the year prior to the

	initiation of federal award support) for the grant from its own resources and other non-federal sources.
Modified Total Direct Cost (MTDC)	*Modified Total Direct Cost (MTDC) means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of indirect costs, and with the approval of the cognizant agency for indirect costs. *This definition applies to rate agreements negotiated on/after 12/27/2014 and to entities without an indirect cost rate agreement using the 10% de minimis rate.
New Application	A request for financial assistance for a project or activity that is not currently receiving support. A new application is required for consideration under a competitive FOA.
Non-Competing Continuation	Funding for the second or subsequent budget period within an approved competitive project period that is released following submission and HRSA approval of a progress report. A non-competing continuation application does not compete with other applications for support. For details and user guides, please visit http://www.hrsa.gov/grants/noncompetingcontinuations/index.html.
Non-Federal Entity	Non-federal entity means a state, local government, Indian tribe, institution of higher education (IHE), or non-profit organization that carries out a federal award as a recipient or subrecipient.
Non-profit Organization	Any corporation, trust, association, cooperative, or other organization, not including IHEs, that: is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized primarily for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization.
Notice of Award (NoA)	The NoA is the official document, signed (or the electronic equivalent of signature) by a GMO that: (1) notifies the recipient of the award of a grant or cooperative agreement; (2) contains or references all the terms and conditions of the grant and federal funding limits and obligations; and, (3) provides the documentary basis for recording the obligation of federal funds in the HRSA accounting system.

Objective Review	An advisory review of discretionary award applications conducted by unbiased reviewers with expertise in the programmatic area for which applications are submitted.
Pre-Award Costs	Costs incurred prior to the beginning date of the project period, in anticipation of an award and at the applicant's own risk, for otherwise allowable costs.
Principal	Per 2 CFR § 180.995, (a) An officer, director, owner, partner, principal investigator, or other person within a participant with management or supervisory responsibilities related to a covered transaction; or (b) A consultant or other person, whether or not employed by the participant or paid with federal funds, who— (1) Is in a position to handle federal funds; (2) Is in a position to influence or control the use of those funds; or, (3) Occupies a technical or professional position capable of substantially influencing the development or outcome of an activity required to perform the covered transaction. Per 2 CFR § 376.995, Individuals, in addition to those listed at 2 CFR § 180.995, who participate in HHS covered transactions including: (a) Providers of federally required audit services; and (b) Researchers.
Program Contact (PC)	HRSA staff person listed in the FOA to answer programmatic questions.
Progress Report	Periodic, usually annual, reports submitted by the recipient and used by HRSA to assess progress and, except for the final progress report, to determine whether to provide funding for the budget period subsequent to that covered by the report.
Project Officer / Program Official (PO)	The PO is the HRSA official responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants/cooperative agreements. The PO's responsibilities include, but are not limited to, development of programs to meet HRSA's mission; preparation of FOAs; provision of programmatic technical assistance; post-award monitoring of project/program performance, including review of progress reports and making site visits; and other activities complementary to those of the GMS. The PO and the GMS work as a team in many of these activities. For the purposes of this document, the PO may also be referred to as the program contact (PC).
Project or Program Costs	The total allowable costs incurred under a federal award and all required cost sharing and voluntary committed cost sharing, including third-party contributions.

Project Period	The total time for which support of a project has been programmatically approved. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a competing continuation award, and any non-competing extensions. Project periods are comprised of 12-month budget periods.
Reasonable Cost	A cost whose nature or amount does not exceed that which would be incurred by a prudent person under the circumstances prevailing when the decision was made to incur the cost.
Recipient	The organization or individual that receives a grant or cooperative agreement award directly from HRSA and is responsible and accountable for the use of the funds provided and for the performance of the HRSA-supported project or activity. The recipient is the entire legal entity even if a particular component is designated in the NoA. The term includes "grantee" and "awardee." The term recipient does not include subrecipients.
Research	A systematic study directed toward fuller scientific knowledge or understanding of the subject studied. "Development" is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes.
Research Misconduct	Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or differences of opinion.
State	Unless otherwise defined in programmatic statute, any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any agency or instrumentality thereof exclusive of local governments. State institutions of higher education and state hospitals are not considered state governments for purposes of the HHS general administrative requirements for grants and the HHS GPS.
Subaward	An award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a federal award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a

	federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract. The term includes consortium agreements.
Subrecipient	A non-federal entity that receives a subaward from a pass-through entity to carry out part of a federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other federal awards directly from a federal awarding agency.
Substantive Programmatic Work	The primary project activities for which award support is provided.
Supplies	Personal property other than equipment, intangible property, and debt instruments. The category of "supplies" includes items that could be considered equipment, but do not meet the threshold definition.
System for Award Management (SAM)	The System for Award Management (SAM) replaced the Central Contractor Registration (CCR) (as of July 30, 2012) and is the central government repository for organizations working with the Federal Government.
Tangible Property	Equipment, supplies, and any other property other than that defined as intangible property. It also does not include copyrights, patents, and other intellectual property that is generated or developed (rather than acquired) under an award.
Terms and Conditions of Award	All legal requirements imposed on an award by HRSA, whether based on statute, regulation, policy, or other document referenced in the NoA, or specified by the NoA itself. In addition to general terms and conditions, the NoA may include other conditions that are considered necessary to attain the award's objectives, facilitate post-award administration, conserve grant funds, or otherwise protect the Federal Government's interests.
Third-Party In-Kind Contributions	The value of non-cash contributions (*i.e.,* property or services) that benefit a federally assisted project or program and are contributed by non-federal third parties, without charge, to a non-federal entity under a federal award. In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.

Total Project or Program Costs	The total allowable costs (inclusive of direct **and** indirect costs) incurred by the recipient to carry out a grant-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement.
Training Project	A type of discretionary award support designed to provide student or staff training in techniques pertaining to research or the delivery of certain services.
Type 1	Brand new HRSA award. Part of a coding system used by HRSA to make distinctions between awards. The award type is the first digit of the "Award No." as indicated in Box 4a of the Notice of Award (NoA). Also see Competing Continuation (Type 2 award) and Competing Supplement (Type 3 award).
Unique Entity Identifier	Unique Entity Identifier is currently the Dun and Bradstreet Data Universal Numbering System (DUNS) number. The DUNS number is the unique entity identification number in use at HRSA. The DUNS number is required information for applicants and recipients in order to complete and maintain their registration in the System for Award Management (SAM). The Uniform Guidance references at 2 CFR § 25.315 – which describes the use of the DUNS number by federal award applicants and recipients.

This list is not all-inclusive. Please refer to 45 CFR § 75.2 Definitions.

2.7. Acronyms

AO Authorizing Official
AOR Authorized Organization Representative
BPHC Bureau of Primary Health Care
BHW Bureau of Health Workforce
CCR Central Contractor Registration (now defunct)
CFDA Catalog of Federal Domestic Assistance
CFR Code of Federal Regulations
CGMO Chief Grants Management Officer
CLAS Culturally and Linguistically Appropriate Services
DCA Division of Cost Allocation
DSO Digital Services Operation
DUNS Data Universal Numbering System
E-Biz POC E-Business Point of Contact
EHBs Electronic Handbooks

EIN	Employer Identification Number
EO	Executive Order
FAIN	Federal Award Identification Number
FAQ	Frequently Asked Questions
FAR	Federal Acquisition Regulation
FFATA	Federal Funding Accountability and Transparency Act
FOA	Funding Opportunity Announcement
FORHP	Federal Office of Rural Health Policy
FY	Fiscal Year
F&A	Facilities and Administration
GMO	Grants Management Officer
GMS	Grants Management Specialist
GPS	Grants Policy Statement
HAB	HIV/AIDS Bureau
HHS	Health and Human Services
HRSA	Health Resources and Services Administration
HSB	Healthcare Systems Bureau
IE	Internet Explorer
MCHB	Maternal and Child Health Bureau
MPIN	Marketing Partner ID Number
MTDC	Modified Total Direct Cost
NCC	Noncompeting Continuation
NHAS	National HIV/AIDS Strategy
NoA	Notice of Award
OFAM	Office of Federal Assistance Management
OMB	Office of Management and Budget
ORO	Office of Regional Operations
OS	Operating System
PC	Program Contact
PD	Project Director
P.L.	Public Law
PMS	Payment Management System
PO	Project Officer / Program Official
POC	Point of Contact
R&R	Research and Related
SAM	System for Award Management
SF	Standard Form
SPOC	Single Point of Contact
TA	Technical Assistance
TIN	Tax Identification Number

3. REGISTERING AND APPLYING THROUGH GRANTS.GOV

HRSA ***requires*** you to apply electronically through Grants.gov.

HRSA suggests submitting applications to Grants.gov at least three days before the deadline to allow for any unforeseen circumstances.

You are responsible for reading and complying with the Grants.gov Online User Guide, available at http://www.grants.gov/help/html/help/index.htm. A short video on how to Register, Find and Apply is available at http://www.youtube.com/watch?v=8HLFoOoVGQY.

Grants.gov requires registration and an annual update to the registration information. **If you do not complete the registration and update it annually, you will not be able to submit an application.**

A five-step registration process must be completed by every organization wishing to apply for a HRSA grant opportunity. The process will take anywhere from five business days to one month. **First-time applicants or those considering applying in the future should register immediately.** Registration with Grants.gov provides the representatives from the organization with the required credentials necessary to submit an application.

3.1. REGISTER – Applicant Organizations Must Obtain DUNS Number, Register with SAM and Grants.gov (if not already registered)

If you have already completed Grants.gov registration for HRSA or another federal agency, confirm that it is still active and that the Authorized Organization Representative (AOR) has been approved, then skip to the next section.

The Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (http://fedgov.dnb.com/webform/pages/CCRSearch.jsp)
- System for Award Management (SAM) (https://www.sam.gov)
- Grants.gov (http://www.grants.gov/)

You will not be able to successfully submit an application or accept an award without active and accurate information in each system.

Registration information provided in these systems is verified among the Internal Revenue System, SAM, and Grants.gov. Therefore, registration information must be consistent in each of the three systems and must be updated annually in SAM. **If you do not complete the registration and update it annually, you will not be able to submit an application in Grants.gov and you will not be eligible for a deadline extension.**

If you need to register with Grants.gov, detailed registration information can be found on Grants.gov under the APPLICANTS tab as Applicant Resources: Organization Registration (http://www.grants.gov/web/grants/applicants/organization-registration.html). These instructions will walk you through the following five basic registration steps:

Step 1: Obtain a Data Universal Numbering System (DUNS) Number
A DUNS number is a unique nine-digit number that identifies an organization. It has been adopted by the Federal Government to help track how federal grant money is distributed. Ask your grant administrator or Chief Financial Officer to provide your organization's DUNS Number. An organization may have more than one DUNS Number, so ensure consistent use of the appropriate organizational DUNS Number in SAM and Grants.gov. If your organization does not have a DUNS Number, you may request one online at http://fedgov.dnb.com/webform or call the Dun & Bradstreet hotline at 1-800-705-5711 (for the U.S. and U.S. Virgin Islands) or 1-800-234-3867 (for Puerto Rico) to receive one free of charge. Once you have completed the registration, your DUNS Number will be available the same day. Note: a missing or incorrect DUNS number is the primary reason for applications being "Rejected for Errors" by Grants.gov.

Step 2: Register with the System for Award Management (SAM)
The System for Award Management (SAM) replaced the Central Contractor Registration (CCR) (as of July 30, 2012) and is the central government repository for organizations working with the Federal Government. In SAM, you must designate the organization's E-Business Point of Contact (E-Biz POC) who will create the organization's Marketing Partner ID Number (MPIN) password. The E-Biz POC will use the MPIN to designate AORs through Grants.gov.

Active SAM registration is a prerequisite to the successful submission of grant applications!

You should monitor the following items:

- When does the SAM account expire?
- Does the organization need to complete the annual renewal of SAM registration?
- Who is the E-Business point of contact (E-Biz POC)? Is this person still with the organization?

To learn more about SAM, please visit https://www.sam.gov. View the SAM Video Tutorial for New Applicants created by the General Services Administration at http://www.youtube.com/watch?v=mmHcKCchaiY. For help using SAM, contact the Service Desk at http://www.FSD.gov.

Note: SAM information must be updated at least every 12 months to remain active (for both awardees and sub-recipients). Annual updates take a minimum of one business

day to take effect in Grants.gov. Grants.gov will reject submissions from applicants with expired registrations. Do not wait until the last minute to register in SAM. As stated in the SAM Quick Start Guide for Grant Registrations (https://www.sam.gov/sam/transcript/Quick_Guide_for_Grants_Registrations.pdf), "Please give yourself plenty of time before your grant application submission deadline. Allow up to 7-10 business days after you submit before your registration is active in SAM, then an additional 24 hours for Grants.gov to recognize your information." The SAM registration must be active before you can proceed to step 3. Therefore, ***check for active registration well before the application deadline.***

If you fail to allow ample time to complete registration with SAM or Grants.gov, you will not be eligible for a deadline extension or waiver of the electronic submission requirement.

Check to see if your organization is already registered at the SAM Web site. If your organization is not registered, identify the primary contact who should register your organization. Visit the SAM Web site at http://www.sam.gov to register online or call 1-888-606-8220 to register by phone. SAM registration must be renewed annually. Before registering, you should review the SAM User Guide at https://www.sam.gov/sam/transcript/System_for_Award_Managementv3.3.pdf. If after having registered in SAM, you experience any registration problems, you can get help from the Federal Service Desk at https://www.fsd.gov.

You must designate the organization's E-Biz POC who will create the organization's Marketing Partner ID Number (MPIN) password. The E-Biz POC will use the MPIN to designate AORs through Grants.gov.

If your organization is registered in SAM, ensure that you renew your SAM registration yearly. If SAM registration expires, you will not be able to apply for or receive funding.

Step 3: **Creating a Username & Password**

- After the SAM registration is complete, return to Grants.gov to establish an Authorized Organization Representative (AOR). Only an AOR is authorized to submit grant applications for your organization.
- AORs must create a short profile and obtain a username and password from the Grants.gov Credential Provider.
- AORs will only be authorized for the DUNS number registered in the Grants.gov profile.

Step 4: AOR Authorization

- The E-Biz POC uses the DUNS number and MPIN to authorize your AOR status.
- Only the E-Biz POC may authorize AORs.
- Only approved/authorized AORs may submit on behalf of an organization.
- AORs that have not been approved by the E-Biz POC will not be able to submit applications through Grants.gov.

Step 5: Track AOR Status

- Using your username and password from Step 3, go to Grants.gov under Applicant Login to check your AOR status at https://apply07.grants.gov/apply/login.faces.

Allow for extra time if you do not have a Tax Identification Number (TIN) or Employer Identification Number (EIN). SAM validates the EIN against Internal Revenue Service records, a step that will take an additional one to five business days.

Additional assistance with the registration process is available at Grants.gov under ORGANIZATION REGISTRATION at http://www.grants.gov/web/grants/applicants/organization-registration.html. In addition, under APPLICANT RESOURCES at http://www.grants.gov/web/grants/applicants/applicant-resources.html a variety of support options are available including FAQs, Glossary, Online User Guide & Checklists, Training, General Support, and Technical Support.

Please direct questions regarding Grants.gov registration to the Grants.gov Call Center at 1-800-518-4726 (International callers, please dial 606-545-5035). Call Center hours of operation are 24 hours a day, 7 days a week, excluding federal holidays. When contacting Grants.gov you should always obtain a case number. You may also receive assistance via email at support@grants.gov or access the Grants.gov Self-Service Knowledge Base at https://grants-portal.psc.gov/Welcome.aspx.

- **NOTE:** It is HIGHLY recommended that this registration process is completed at least TWO WEEKS prior to the submittal date of your organization's first Grants.gov submission.

3.2. APPLY - Apply through Grants.gov

Grants.gov includes a simple, unified application process to enable you to apply for grants online. The information you need to register and submit your application online can be found at Grants.gov under the APPLICANTS *tab* under *Apply for Grants* (http://www.grants.gov/web/grants/applicants/apply-for-grants.html). The site also contains an *Online User Guide* athttp://www.grants.gov/help/html/help/index.htm.

The application will be one of three announcement types indicated on the cover of the FOA: new, competing continuation, or competing supplement. All competing applications are submitted electronically to HRSA through Grants.gov using the Application for Federal Assistance SF-424 R&R form.**

**If you are applying for awards that require the SF-424 Non-Construction application package, you must refer to HRSA's *SF-424 Application Guide* for guidance.

3.2.1. Find Funding Opportunity

If you are submitting a competing application, search for the announcement in Grants.gov by clicking the SEARCH GRANTS tab (http://www.grants.gov/web/grants/search-grants.html), entering the FOA number and then selecting the announcement for which you wish to apply. Refer to the FOA for eligibility criteria.

If you are an existing awardee and are submitting a competing continuation or competing supplement application, search for the announcement under the APPLICANTS tab under *Apply for Grants* (http://www.grants.gov/web/grants/applicants/apply-for-grants.html). Enter the announcement number provided in the field, Funding Opportunity Number. (Example announcement number: HRSA-16-001.)

3.2.2. Download Application Package

Download the application package and instructions. Application packages are posted in Adobe Reader format. To ensure that you can view the application package and instructions, you should download and install the Adobe Reader application. The application package will be saved to your computer, completed offline, and then uploaded to Grants.gov at the time of submission.

For more information on using Adobe Reader, refer to Section 8.1.2.

- **NOTE:** Please review the system requirements for Adobe Reader at http://www.grants.gov/web/grants/support/technical-support/recommended-software.htm.

3.2.3. Complete the Grant Application Package

Complete the application using both the built-in instructions and the instructions provided in the FOA. You may complete the application offline – you are not required to be connected to the Internet. Ensure that you save a copy of the application on your computer. For assistance with program guidance related questions, please contact the Program Contact (PC) listed in Section VII of the FOA. For assistance with budget or other administrative related questions, please contact the Grants Management Specialist (GMS) listed in Section VII of the FOA.

- **NOTE:** Awardees with competing continuations and competing supplements should provide their 10-digit grant number [box 4b from the NoA] in the Federal Identifier field (box 4.a. in SF-424 R&R).

3.2.4. Submit a Completed Application Package

Once you have downloaded the application package, completed all required forms, and attached all required documents—click the "Check Package for Errors" button and make any necessary corrections.

- In Adobe Reader, click on the "Save and Submit" button when you have done all of the above and are ready to send your completed application to Grants.gov.

Review the provided application summary to confirm that the application will be submitted to the program for which you wish to apply. **If you submit an application to the wrong announcement number, you must apply to the correct announcement number on or before the posted deadline**. To submit, **the AOR** must login to Grants.gov and enter their username and password. Note: the same DUNS number, AOR username, and password must be used to complete and submit your application. Once you have logged in, your application package will automatically be uploaded to Grants.gov. A confirmation screen will appear once the upload is complete. Note that a Grants.gov Tracking Number will be provided on this screen (GRANTXXXXX). Please record this number so that you may refer to it for all subsequent help.

Please direct questions regarding application submission to the Grants.gov Call Center at 1-800-518-4726 (International callers, please dial 606-545-5035). Call Center hours of operation are 24 hours a day, 7 days a week, excluding federal holidays.

- **NOTE:** The AOR must be connected to the Internet and must have a Grants.gov username and password associated with the correct DUNS number in order to submit the application package.

3.2.5. Verify Status of Application in Grants.gov

Once Grants.gov has received your submission, Grants.gov will send email messages to the Project Director (PD), Authorized Organizational Representative (AOR), and the Point of Contact (POC) listed in the application advising of the progress of the application through the system. You will receive up to four emails. The first will confirm receipt of your application by the Grants.gov system ("Received"), and the second will indicate that the application has either been successfully validated ("Validated") by the system prior to transmission to the grantor agency or has been rejected due to errors ("Rejected with Errors"). **An application for HRSA funding must be both received and validated by Grants.gov by the application deadline.**

Upon submission, Grants.gov will attempt to validate the application. This validation ensures that the AOR has submitted the application and that all required standard forms are complete and have the correct type of information in them. Grants.gov will also validate that your SAM registration is current. Grants.gov will not validate application content, attachments, page limit, or your organization's eligibility.

If your application is rejected due to an error, you must correct the application and resubmit it to Grants.gov before the posted deadline. The full verification process may take hours to days, therefore, you need to allow plenty of time. If you are unable to resubmit because the opportunity has since closed, you must follow the instructions in **Section 3.6** to request a waiver.

You can check the status of your application(s) any time after submission by visiting Grants.gov's Track My Application page at http://www.grants.gov/web/grants/applicants/track-my-application.html. This link will also be included in the confirmation email that you receive from Grants.gov.

If there are no errors, the application will be downloaded by HRSA. Upon successful download to HRSA, the status of the application will change to "Received by Agency" and the contacts listed in the application will receive a third email from Grants.gov. Once your application is received by HRSA, it will be processed to ensure that the application is submitted for the correct funding announcement, with the correct grant number (if applicable), and applicant/awardee 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." You will receive the fourth email in which Grants.gov will provide the Agency Tracking Number. Record the Agency tracking number and use it for all correspondence with HRSA.

3.3. Receipt Acknowledgement

In summary, upon receipt of an application, Grants.gov will send a series of email messages to document the progress of an application through the system.

1) The first will confirm receipt in the system;
2) The second will indicate whether the application has been successfully validated or has been rejected due to errors;
3) The third will be sent when the application has been successfully downloaded at HRSA; and
4) The fourth will notify you of the Agency Tracking Number assigned to the application.

If you are trying to track your application and you have not received any emails from Grants.gov, be sure to check your spam folder. Sometimes the emails from Grants.gov are blocked by your email service.

3.4. Tracking Your Application

It is incumbent on you to track your application by using the Grants.gov tracking number (GRANTXXXXXXXX) provided in the confirmation email from Grants.gov. More information about tracking an application can be found at http://www.grants.gov/web/grants/applicants/track-my-application.html. Be sure the

application is validated by Grants.gov (under the correct funding opportunity number) prior to the application deadline.

3.5. Late Applications

Applications which do not meet the criteria as outlined in Section IV of the FOA will be considered late applications and will not be considered in the current competition.

3.6. Requesting a Waiver from the Electronic Submission Requirement

HRSA ***requires*** you to apply electronically through Grants.gov and have the application validated under the correct funding opportunity number on or before the deadline date and time. The registration and application process protects you against fraud and ensures that only authorized representatives from an organization can submit an application. You are responsible for maintaining these registrations, which should be completed well in advance of submitting an application. You ***must*** submit in this manner unless they obtain a written exemption from this requirement, within five calendar days of the opportunity's closing date, by the Director of HRSA's Division of Grants Policy.

You must request an exemption in writing from **DGPWaivers@hrsa.gov**, and provide details as to why you are technologically unable to submit electronically through the Grants.gov portal. If requesting a waiver from the electronic submission requirements, include the following in the e-mail request: the HRSA announcement number for which the organization is seeking relief; the organization's name, address, and telephone number; the organization's DUNS number; the name, address, and telephone number of the PD; as well as the Grants.gov Tracking Number (GRANTXXXXXXXX) assigned to the submission along with a copy of the "Rejected with Errors" notification as received from Grants.gov, if applicable. If case numbers were given from calling Grants.gov, please include those as well. HRSA's Division of Grants Policy is the only office authorized to grant waivers.

HRSA and its Digital Services Operation (DSO) will only accept paper applications from applicants that received prior written approval. However, the application must still be validatedby the deadline. Suggestion: submit application to Grants.gov at least three days before the deadline to allow for any unforeseen circumstances.

HRSA is very strict on adhering to application deadlines and electronic submission requirements. Deadline extensions will not be granted for Grants.gov verification errors, last-minute registration, or submission errors on the part of the applicant. The CGMO or designee may consider an extension of published deadlines or allowance of a submission outside of the Grants.gov system, when justified by circumstances such as natural disasters (e.g., floods or hurricanes), other disruptions of services, such as a

prolonged blackout, or in the rare event of a validated technical issue on the side of the government that prevented applicants from applying before the deadline. The CGMO or designee will determine the affected geographical area(s).

4. GENERAL INSTRUCTIONS FOR APPLICATION SUBMISSION

HRSA ***requires*** you to apply electronically through Grants.gov. You must download the Standard Form 424 Research and Related (SF-424 R&R) application package associated with the funding opportunity following the directions provided at Grants.gov.

The following instructions are applicable to all submissions unless otherwise noted in the relevant FOA. Failure to follow the instructions may make your application non-responsive. Non-responsive applications will not be given any consideration and the particular applicants will be notified. It is mandatory to follow the instructions provided to ensure that your application can be printed efficiently and consistently for review.

4.1. Instructions for Completing the SF-424 R&R

i. Application Face Page

Complete Application Form SF-424 R&R provided with the application package. Prepare according to instructions provided in the form itself.

DUNS Number

Your organization (and subrecipients of HRSA award funds) is required to have a DUNS number in order to apply for a grant or cooperative agreement from the Federal Government. Please include the DUNS number in form SF-424 R&R - item 5 on the application face page. Applications ***will not*** be reviewed without a DUNS number. Note: A missing or incorrect DUNS number is the number one reason for applications being “Rejected for Errors” by Grants.gov. HRSA will not extend the deadline for applications with a missing or incorrect DUNS number. You should take care in entering the correct DUNS number in the application.

Additionally, your organization (and any subrecipient of HRSA award funds) is required to register annually with SAM in order to conduct electronic business with the Federal Government. SAM registration must be maintained with current, accurate information at all times during which an entity has an active award or an application or plan under consideration by HRSA. It is extremely important to verify that your organization’s SAM registration is active and the Marketing Partner ID Number (MPIN) is current. Organizations will not be able to submit an application or accept an award if SAM registration is not complete and accurate. Information about registering with SAM can be found at https://www.sam.gov.

CFDA Number
The Catalog of Federal Domestic Assistance (CFDA) Number, as listed on the cover of the FOA, is prepopulated in box 10 of the form.

ii. Intergovernmental Review (Executive Order (EO) 12372)
If an FOA is subject to EO 12372, "Intergovernmental Review of Federal Programs," or not it will be stated in Section IV.5. Intergovernmental Review of the FOA. Please refer to #16 on the SF-424 R&R.

If intergovernmental review applies, the following language will appear in the FOA:

> PROGRAM NAME is a program subject to the provisions of Executive Order (EO) 12372, as implemented by 45 CFR part 100. See Executive Order 12372 in the HHS Grants Policy Statement.

EO 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain federal programs. Information on States that have chosen to set up such a review system and corresponding State Points of Contact may be obtained from the following Web site: http://www.whitehouse.gov/omb/grants_spoc.

All applicants other than federally recognized Native American tribes or tribal organizations should contact their SPOC as early as possible to alert them to the prospective applications and receive any necessary instructions on the state's process used under this EO.

iii. Table of Contents
The application should be presented in the order of the Table of Contents provided in Section 4.3 of this *SF-424 R&R Application Guide*. Again, for electronic applications no table of contents is necessary as it will be generated by the system. (Note: the Table of Contents will not be counted in the page limit.)

iv. Budget
Note: the directions here may differ from those offered by Grants.gov. Please follow the instructions included in the program-specific FOA and the instructions below when completing the project budget forms.

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

Classification of Costs:
There is no universal rule for classifying certain costs as either direct or indirect (F&A) under every accounting system. A cost may be direct with respect to some specific service or function, but indirect with respect to the federal award or other final cost objective. Therefore, it is essential that each item of cost incurred for the same purpose be treated consistently in like circumstances either as a direct or an indirect (F&A) cost in order to avoid possible double-charging of federal awards. Guidelines for determining direct and indirect (F&A) costs charged to federal awards are provided in 45 CFR part 75, subpart E.

Research & Related Budget:
Please complete the Research & Related Budget form included with the application package (Sections A – J and the Cumulative Budget) for each budget period. While up to five budget periods are available on the form, refer to the grant specific guidelines for the maximum number of budget periods allowed in the grant program for which you are applying. Following completion of Budget Period 1, click on the "NEXT PERIOD" button on the final page to allow for completion of Budget Period 2. Repeat this instruction to complete any remaining Budget Periods.

The Cumulative Budget is automatically generated and provides the total budget information for the grant request. Errors found in the Cumulative Budget must be corrected within the incorrect field(s) in all Budget Periods; corrections cannot be made to the Cumulative Budget itself.

If the FOA notes that the program is subject to the General Provisions of P.L.114-113, the following Salary Limitation applies:

Salary Limitation:
The General Provisions in Division H, § 202, of the Consolidated Appropriations Act, 2016 (P.L. 114-113), includes provisions for a salary rate limitation. The law limits the salary amount that may be awarded and charged to HRSA grants and cooperative agreements. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II. The Executive Level II salary of the Federal Executive Pay scale is $185,100. This amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to your organization. This salary limitation also applies to subrecipients under a HRSA grant or cooperative agreement. Note that these or other salary limitations will apply in FY 2016, as required by law.

As an example of the application of this limitation: If an individual's base salary is $255,000 per year plus fringe benefits of 25% ($63,750) and that individual is devoting 50%/half of their time to this award, their base salary should be adjusted to $185,100 plus fringe at 25% of half this amount ($23,137.50) and a total of $115,687.50 may be included in the project budget and charged to the award for salary/fringe benefits for that individual. See the breakdown below:

Individual's *actual* base full time salary: $255,000 50% of time will be devoted to project	
Direct salary	$127,500
Fringe (25% of salary)	$31,875
Total	$159,375
Amount that may be claimed on the application budget due to the legislative salary limitation: Individual's base full time salary *adjusted* to Executive Level II: $185,100 50% of time will be devoted to the project	
Direct salary	**$92,550**
Fringe (25% of salary)	**$23,137.50**
Total amount	**$115,687.50**

Funding Restrictions (in general)
You may request no more than the ceiling amount listed in Section II.2. Summary of Funding and Section IV.6. Funding Restrictions of the FOA. Awards to support projects will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that funding would be in the best interest of the Federal Government.

The governing cost principles address selected items of cost. The FOA specifies unallowable costs that apply to each funding opportunity. The following list of unallowable costs is not intended to be all-inclusive. The cost principles should be consulted for the complete explanation of the allowability or unallowability of costs they address. For the full list of cost principles refer to Section 2.3 "Compliance Requirements at a Glance" to see which cost principles apply to your organization and refer to Subpart E – Cost Principles at 45 CFR part 75. The allowability of costs under individual HRSA awards also may be governed by requirements specified in the program legislation, regulations, or the specific terms and conditions of the award, which will take precedence over the general information provided here.

Item	Description
Advertising and Public Relations	Conditionally allowable. See 45 CFR § 75.421 for details.
Advisory Councils	Costs incurred by advisory councils or committees are unallowable **unless** authorized by statute, the HHS awarding agency or as an indirect cost where allocable to federal awards. See 45 CFR § 75.444, applicable to states, local governments and Indian Tribes.
Alcoholic Beverages	Unallowable as an entertainment expense.
Bad Debts	Unallowable.
Entertainment Costs	Conditinally unallowable. This includes the cost of

	amusements, social activities, and related incidental costs. 45 CFR § 75.438 clarifies when entertainment costs may be charged to a federal award with prior approval.
Fundraising Costs	Unallowable.
Honoraria	Unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, such as a speaker's fee under a conference grant, is allowable.
Invention, Patent, or Licensing Costs	Unallowable as a direct cost unless specifically authorized in the NoA. May be allowable as indirect costs provided they are authorized under applicable cost principles and are included in the negotiation of indirect cost rates. Such costs include licensing or option fees, attorney's fees for preparing or submitting patent applications, and fees paid to the U.S. Patent and Trademark Office for patent application, patent maintenance, or recordation of patent-related information.
Lobbying	Generally unallowable, including costs of lobbying activities to influence the introduction, enactment, or modification of legislation by the U.S. Congress or a state legislature. Under certain circumstances, as provided in the applicable cost principles, costs associated with activities that might otherwise be considered "lobbying" that are directly related to the performance of a grant or cooperative agreement may be allowable. The recipient should obtain an advance understanding with the GMS if it intends to engage in these activities. See "Restriction on Lobbying" below and at 45 CFR § 75.450 for additional descriptions and examples of prohibited activities. View a webinar on "The Ins and Outs of Lobbying for HRSA Grantees" at http://services.choruscall.com/links/hrsa141028.html.
Meals	Generally unallowable except for the following: • Subjects and patients under study • Where specifically approved as part of the project or program activity, e.g., in programs providing children's services • When an organization customarily provides meals to employees working beyond the normal workday, as a part of a formal compensation arrangement • As part of a per diem or subsistence allowance provided in conjunction with allowable travel. Under a conference grant, when meals are a necessary and

	integral part of a conference, provided that meal costs are not duplicated in participants' per diem or subsistence allowances. Guest meals are not allowable. (See "Consumer/Provider Board Participation" in Definitions section regarding the allowability of the cost of meals for consumer and provider board participants in federal award-supported activities.)
Pre-award Costs	Costs incurred prior to the effective date of the sponsored agreement, whether or not they would have been allowable thereunder if incurred after such date, are unallowable unless approved by the federal agency or authorized under expanded authority. Where authorized by the sponsoring agency as an expanded authority, a recipient may, at its own risk and without sponsoring agency prior approval, incur obligations and expenditures to cover costs up to (and including) 90 days before the beginning date of the initial budget period of a new or competing continuation award if such costs • are necessary to conduct the project or program, and • would be allowable under the grant or cooperative agreement, if awarded. However, even if authorized as an expanded authority, if a specific expenditure would otherwise require prior approval, the cost or activity must meet the same tests of allowability as if incurred after award. If not authorized as part of expanded authorities, the applicant/recipient must seek sponsoring agency prior approval before incurring pre-award costs. Sponsoring agency prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award.
Promotional Items (SWAG)	Promotional items and memorabilia (SWAG e.g., pencils, cups, t-shirts, cookbooks, bags, etc.), gifts, and souvenirs designed to promote the recipient's organization are unallowable as advertising/public relations costs.

Funding Restrictions: If the FOA notes that the program is subject to the General Provisions of P.L. 114-113, the following legislative mandates are in effect:

1. Salary Limitation (Section 202)
2. Gun Control (Section 210)
3. Anti-Lobbying (Section 503)
4. Acknowledgment of Federal Funding (Section 505)
5. Restriction on Abortions (Section 506)
6. Exceptions to Restriction on Abortions (Section 507)
7. Ban on Funding Human Embryo Research (Section 508)
8. Limit on Use of Funds for Promotion of Legalization of Controlled Substances (Section 509)
9. Dissemination of False or Misleading Information (Section (515(b))
10. Restriction on Distribution of Sterile Needles (Section 520)
11. Restriction of Pornography on Computer Networks (Section 521)
12. Restriction on Funding ACORN (Section 522)

Details:

1. Salary Limitation (Section 202)

   "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II."

   The Executive Level II salary increased to $185,100 effective January 10, 2016.

   This amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to the applicant organization. This salary limitation also applies to subawards/subcontracts under an HRSA grant or cooperative agreement.

2. Gun Control (Section 210)

   “None of the funds made available in this title may be used, in whole or in part, to advocate or promote gun control.”

3. Anti-Lobbying (Section 503)

   “ (a) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111–148 shall be used, other than for normal and recognized executive legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

   (b) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111–148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

   (c) The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control."

4. Acknowledgment of Federal Funding (Section 505)

   "When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds included in this Act, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state – (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources."

5. Restriction on Abortions (Section 506)

   "(a) None of the funds appropriated in this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for any abortion.

   (b) None of the funds appropriated in this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortion.

   (c) The term ''health benefits coverage'' means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement."

6. Exceptions to Restriction on Abortions (Section 507)

   "(a) The limitations established in the preceding section shall not apply to an abortion – (1) if the pregnancy is the result of an act of rape or incest; or (2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

   (b) Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State's or locality's contribution of Medicaid matching funds).

(c) Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State's or locality's contribution of Medicaid matching funds).

(d)(1) None of the funds made available in this Act may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.

(d)(2) In this subsection, the term ''health care entity'' includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan."

7. Ban on Funding of Human Embryo Research (Section 508)

"(a) None of the funds made available in this Act may be used for – (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term ''human embryo or embryos'' includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

8. Limitation on Use of Funds for Promotion of Legalization of Controlled Substances (Section 509)

"(a) None of the funds made available in this Act may be used for any activity that promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the

Controlled Substances Act except for normal and recognized executive-congressional communications.

(b)The limitation in subsection (a) shall not apply when there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage."

9. Dissemination of False or Deliberately Misleading Scientific Information (Section 515(b))

   “None of the funds made available in this Act may be used to disseminate information that is deliberately false or misleading.”

10. Restriction on Distribution of Sterile Needles (Section 520)

    "Notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug: Provided, That such limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with State and local law.”

11. Restriction of Pornography on Computer Networks (Section 521)

    “(a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

    (b) Nothing in subsection (a) shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities.”

12. Restrictions on Funding ACORN (Section 522)

"None of the funds made available under this or any other Act, or any prior Appropriations Act, may be provided to the Association of Community Organizations for Reform Now (ACORN), or any of its affiliates, subsidiaries, allied organizations, or successors."

v. Budget Justification Narrative

Upload the Budget Justification narrative for the entire project period (**all** budget periods) in Section K of the Research & Related Budget Form. Provide a budget narrative that explains the amounts requested for each line of the budget in Sections A-F. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the "other" category is justified. For subsequent budget years, the narrative should highlight the changes from year one or clearly indicate that there are no substantive budget changes during the project period. Do NOT use the budget narrative to expand the project narrative.

Budget for Multi-Year Award (project periods vary, maximum of five years)
FOAs invite applications for project periods of one to up to five years. Generally, awards, on a competitive basis, will be for a one-year budget period; although the project period may be up to five years. Submission and HRSA approval of the Progress Report(s) and any other required submission or reports is the basis for the budget period renewal and release of subsequent year funds. Funding beyond the one-year budget period but within the multi-year project period is subject to availability of funds, satisfactory progress of the awardee, and a determination that continued funding would be in the best interest of the Federal Government.

In addition to requirements included in the program-specific FOA, include the following in the Budget Justification narrative:

Personnel Costs (as listed in Sections A & B on the R&R Budget Form):
Personnel costs should be explained by listing each staff member who will be supported from funds, name (if possible), position title, percentage of full-time equivalency, and annual salary. If the FOA notes that the program is subject to the General Provisions of P.L. 114-113, the following applies: Reminder: Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II or $185,100. An individual's base salary, per se, is NOT constrained by the legislative provision for a limitation of salary. The rate limitation simply limits the amount that may be awarded and charged to HRSA grants and cooperative agreements. Please provide an individual's actual base salary if it exceeds the cap. See the sample below.

Sample:

Name	Position Title	% of FTE	Annual Salary	Amount Requested
J. Smith	Chief Executive Officer	50	$185,100*	$92,550
R. Doe	Nurse Practitioner	100	$75,950	$75,950
D. Jones	Data/AP Specialist	25	$33,000	$8,250

*Actual annual salary = $255,000

Fringe Benefits (as listed in Sections A & B on the R&R Budget Form): List the components that comprise the fringe benefit rate, for example health insurance, taxes, unemployment insurance, life insurance, retirement plans, and tuition reimbursement. The fringe benefits should be directly proportional to that portion of personnel costs that are allocated for the project. If the FOA notes that the program is subject to the General Provisions of P.L. 114-113, the following applies: If an individual's base salary exceeds the legislative salary cap (i.e., $185,100), adjust fringe proportionally.

Equipment (as listed in Section C on the R&R Budget Form): 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 when requesting funds for the purchase of items that meet the definition of equipment (a unit cost of $5,000 or more and a useful life of one or more years).

Travel (as listed in Section D on the R&R Budget Form): List travel costs according to local and long distance travel. For local travel, the mileage rate, number of miles, reason for travel and staff member/consumers completing the travel should be outlined. The budget should also reflect the travel expenses (e.g., airfare, lodging, parking, per diem, etc.) for each person and trip associated with participating in meetings and other proposed trainings or workshops. Name the traveler(s) if possible, describe the purpose of the travel, provide number of trips involved, the destinations, and the number of individuals for whom funds are requested.

Participant/Trainee Support Costs, if applicable (as listed in Section E on the R&R Budget Form): List tuition/fees/health insurance, stipends, travel, subsistence, other and the number of participants/trainees.

Other Direct Costs (as listed in Section F on the R&R Budget Form) include the following, if applicable:

Materials and Supplies: List the items that the project will use to implement the proposed project. Separate items into three categories: office supplies (e.g., paper, pencils), medical supplies (e.g., syringes, blood tubes, gloves), and

educational supplies (e.g., brochures, videos). Remember, they must be listed separately.

Per Subpart D 2 CFR § 200.314 (as codified by HHS at 45 CFR § 75.321), Property will be classified as supplies if the acquisition cost is under $5,000. Note that items such as laptops, tablets, and desktop computers are classified as a supply if the value is under the $5,000 equipment threshold.

Publication Costs: List the total publication funds requested. The proposal budget may request funds for the costs of documenting, preparing, publishing or otherwise making available to others the findings and products of the work conducted under the award. In the budget justification include supporting information.

Consultant Services: List the total costs for all consultant services. In the budget justification, identify each consultant, the services he/she will perform, total number of days, travel costs, and total estimated costs.

ADP/Computer Services: List total funds requested for ADP/Computer Services. The cost of computer services, including computer-based retrieval of scientific, technical and education information may be requested. In the budget justification, include the established computer service rates at the proposing organization if applicable.

Subawards/Consortium/Contractual Costs: Provide a clear explanation as to the purpose of each subaward/contract, how the costs were estimated, and the specific contract deliverables. You are responsible for ensuring that your organization or institution has in place an established and adequate procurement system with fully developed written procedures for awarding and monitoring all contracts. Reminder: recipients must notify potential subrecipients that entities receiving subawards must be registered in SAM and provide the recipient with their DUNS number.

Per the Suspension and Debarment rules in the Uniform Guidance, as implemented by HRSA at 45 CFR § 75.212, non-federal entities and contractors are subject to the non-procurement debarment and suspension regulations implementing Executive Orders 12549 and 12689, 2 CFR parts 180 and 376. These regulations restrict awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in federal assistance programs or activities.

Equipment or Facility Rental/User Fees: List total funds requested for Equipment or Facility Rental/Use Fees. In the budget justification, identify each rental user fee and justify.

Alterations and Renovations: List total funds requested for Alterations & Renovations. In the budget justification, itemize, by category and justify the costs of alterations and renovations including repairs, painting, removal or installation of partitions, shielding, or air conditioning. Where applicable, provide the square footage and costs.

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

You may include the cost of access accommodations as part of their project's budget, including sign interpreters, plain language and health literate print materials in alternate formats (including Braille, large print, etc.); and cultural/linguistic competence modifications such as use of cultural brokers, translation or interpretation services at meetings, clinical encounters, and conferences, etc.

Data Collection Activities: Funds may be used to support appropriate and justifiable costs related to meeting evaluation and reporting requirements. Identify and justify how these funds will be used under the appropriate budget category (personnel, contractual or other).

Indirect Costs: Indirect costs are those costs incurred for common or joint objectives which cannot be readily and specifically identified with a particular project or program but are necessary to the operations of the organization, e.g., the cost of operating and maintaining facilities, depreciation, and administrative salaries. For some institutions, the term "facilities and administration" is used to denote indirect costs. If your organization does not have an indirect cost rate, you may wish to obtain one through HHS's Division of Cost Allocation (DCA). Visit DCA's website at https://rates.psc.gov/ to learn more about rate agreements, the process for applying for them, and the regional offices which negotiate them. If indirect costs are included in the budget, please attach a copy of the indirect cost rate agreement. If the indirect cost rate agreement is required per the FOA, it will not count toward the page limit. Any non-federal entity that has never received a negotiated indirect cost rate, (except a governmental department or agency unit that receives more than $35 million in direct federal funding) may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. If chosen, this methodology once elected must be used consistently for all federal awards until such time as a non-federal entity chooses to negotiate for a rate, which the non-federal entity may apply to do at any time.

vi. Staffing Plan and Personnel Requirements

You must present a staffing plan and provide a justification for the plan that includes education and experience qualifications and rationale for the amount of time being requested for each staff position. Position descriptions that include the roles, responsibilities, and qualifications of proposed project staff must be included in the Attachment *specified in the FOA*. When applicable, biographical sketches should include training, language fluency and experience working with the cultural and linguistically diverse populations that are served by their programs. They should follow the format described below and as laid out in Appendix A:

Professional Information: At the top of page 1, include Name, Position Title, Education/Training including: institution and location, degree, month/year degree attained, field of study. Then complete sections A, B, C, and D as described below.

NOTE: The Biographical Sketch may not exceed five pages. Please refer to the FOA that may restrict the page limit further. Follow the formats and instructions below.

A. Personal Statement

Briefly describe why you are well-suited for your role(s) in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Contribution to Science

Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or

equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. HRSA's Division of Independent Review policy does not allow for linking to information outside the application itself; therefore, please provide abstracts or short descriptions of any key relevant publications that you think are important to share in the Appendix, keeping in mind that the appendices / any attachments count in the overall page limit specified in the FOA.

D. Research Support

List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). *Begin with the projects that are most relevant to the research proposed in the application.* Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

Don't confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, "Research Support" highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, "Other Support" information is required for all applications that are selected to receive grant awards. HRSA staff will request complete and up-to-date "other support" information from you after peer review. This information will be used to check that the proposed research has not already been Federally-funded.

vii. Assurances

Complete Application Form SF-424B Assurances – Non-Construction Programs.

If research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR part 46), available online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.
NOTE: Please see Appendix B of this *SF-424 R&R Application Guide* for supplemental instructions for preparing the human subjects section of the research plan.

If research involving human subjects is anticipated, you must hold a Federal Wide Assurance (FWA) of compliance from the Office of Human Research Protections (OHRP) prior to award. You must provide your Human Subject Assurance Number (from their FWA) in the application; if you do not have an assurance, you must indicate in the application that you will obtain one from OHRP prior to award.

viii. Certifications

The signature of the AOR on the application serves as the required certification of compliance for the applicant organization for the following:

Lobbying

1) No federal appropriated funds have been paid or will be paid, by or on behalf of the applicant, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any federal contract, the making of any federal grant, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative agreement.

2) If any funds other than federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this federal contract, grant, loan, or cooperative agreement, the applicant must complete and submit Standard Form-LLL, "Disclosure of Lobbying Activities," in accordance with its instructions.

3) Recipients of HRSA awards shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly. This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Federal Debt

Any organization or individual that is indebted to the United States, and has a judgment lien filed against it for a debt to the United States, is ineligible to receive a federal grant. By signing the SF-424 R&R, the applicant is certifying that they are not delinquent on federal debt in accordance with OMB Circular A-129. (Examples of relevant debt include delinquent payroll or other taxes, audit disallowances, guaranteed and direct student loans, benefits that were overpaid, etc.). If an applicant is delinquent on federal debt, they should attach an explanation that includes proof that satisfactory arrangements have been made with the Agency to which the debt is owed. This explanation should be uploaded as an Attachment.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

By submitting this proposal, the prospective recipient is providing the certification set out below:

A. This certification in this clause is a material representation of fact. If it is later determined that the prospective recipient knowingly submitted an erroneous certification, in addition to other remedies available to the Federal Government, the Department may pursue available remedies, including but not limited to, suspension and/or debarment.
B. The prospective recipient shall provide immediate written notice to HRSA if at any time the recipient learns that its certification was erroneous when submitted, or had become erroneous due to changed circumstances.
C. The terms covered transaction, debarred, suspended, ineligible, lower tier covered transaction, participant, person, primary covered transaction, principal, proposal, and voluntarily excluded, as used in this certification, are defined in 2 CFR part 180, as supplemented by 2 CFR part 376.
D. The prospective recipient agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is proposed for debarment under 2 CFR part 180 or 48 CFR part 9, subpart 9.4, debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized in writing by HRSA.
E. The prospective recipient further agrees by submitting this proposal that it will include this clause titled ``Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion,'' without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions, and receive a copy of the signed attestation by such lower tier contractor/subawardee.
F. A recipient may rely upon a certification of a prospective recipient in a lower tier covered transaction that neither it nor its principals, are proposed for debarment under 2 CFR part 180 or 48 CFR part 9, subpart 9.4, debarred, suspended, ineligible, or voluntarily excluded from covered transactions, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. HRSA strongly encourages each participant to check the Excluded Parties database in the System for Award Management at https://www.sam.gov.
G. Nothing contained in this certification requires establishment of a system of records in order to provide the certification required by this certification.
H. Except for transactions authorized under paragraph E of this statement, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is proposed for debarment under 2 CFR part 180 or 48 CFR part 9, subpart 9.4, suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the Department may pursue available remedies, including, but not limited to, suspension and/or debarment.

ix. Project Summary/Abstract

Provide a summary of the application. Because the abstract is often distributed to provide information to the public and Congress, please prepare this so that it is clear, accurate, 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 services, and the population group(s) to be served. See the FOA for additional information that may be required in the project abstract.

Please place the following at the top of the abstract:

- Project Title
- Applicant Organization Name
- Address
- Project Director Name
- Contact Phone Numbers (Voice, Fax)
- E-Mail Address
- Web Site Address, if applicable
- List all grant program funds requested in the application, if applicable
- If requesting a funding preference, priority, or special consideration as outlined in Section V. 2. of the program-specific FOA, please indicate here.

The project abstract must be single-spaced and limited to one page in length.

x. Project Narrative

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

xi. Attachments

Provide the attachments as specified in the FOA to complete the content of the application. Please note that these are supplementary in nature, and are not intended to be a continuation of the project narrative. Unless otherwise noted, attachments count toward the application page limit specified in the FOA. **Each attachment must be clearly labeled**.

4.2. Narrative and Attachment Formatting Guidelines

4.2.1. Font

Please use an easily readable font, such as Times Roman, Arial, Courier, or CG Times. The text and table portions of the application must be single-spaced and submitted in not less than a 12-point font. Applications not adhering to 12-point font requirements may be deemed non-responsive and returned. For charts, graphs, footnotes, and budget tables, you may use a different pitch or size font but not less than 10 pitch or size font. It is vital that the charts are legible when scanned or reproduced.

4.2.2. Paper Size and Margins

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

4.2.3. Names

Include the name of the applicant and 10-digit grant number (if competing continuation or competing supplement) on each page as a footer.

4.2.4. Section Headings

Put all section headings flush left in bold type.

4.2.5. Page Numbering

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

4.2.6. Allowable Attachment or Document Types

Unless otherwise noted in the FOA, please do not submit organizational brochures or other promotional materials, slides, films, clips, etc.

The attachment types listed below are supported in HRSA EHBs. Although Grants.gov allows you to upload other types of attachments, **HRSA only accepts the following types of attachments. Files with unrecognizable extensions may not be accepted or may be corrupted, and will not be considered as part of the application**. When the application is printed by HRSA, documents will print as they are formatted by the applicant. If using Excel or other spreadsheet documents, be aware that reviewers will only see information that is set in the "Print Area" of the document.

File Attachment Types (acceptable by HRSA)

- .DOC/.DOCX - Microsoft Word
- .RTF - Rich Text Format
- .TXT - Text
- .WPD - Word Perfect Document
- .PDF - Adobe Portable Document Format
- .XLS/.XLSX - Microsoft Excel
- .VSD – Microsoft Visio

File Attachment Names

- Please use only the following characters when naming your attachments: A-Z, a-z, 0-9, underscore (_), hyphen (-), space ( ), period, parenthesis (), curly braces {}, square brackets [], ampersand &, tilde ~, exclamation point !, Comma , Semicolon; Apostrophe ', At sign @, Number sign #, Dollar Sign $, Percent Sign %, Plus sign +, Equal sign =. Limit the file attachment name to under 50 characters.

Your application may be rejected by Grants.gov if you use attachment names greater than 50 characters.

4.3. Application Content Order (Table of Contents)

HRSA uses an automatic numbering approach to ensure uniformity of all applications when printed for objective review.

HRSA uses a standard package from Grants.gov (SF-424 R&R) and has defined a standard order of forms (see the table on the next two pages). The FOA also provides you with explicit instructions where to upload specific Attachments 1 to maximum of 15.

SF-424 R&R – Table of Contents

- It is mandatory to follow the instructions provided in this section to ensure that the application can be printed efficiently and consistently for review. If an Attachment is not applicable to HRSA and should not be completed, it will be noted in the last column, "HRSA/Program Guidelines."
- Failure to follow the instructions may make the application non-responsive. Non-responsive applications will not be considered.
- For electronic submissions, you 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.

Application Section	Form Type	Instruction	HRSA/Program Guidelines
SF-424 R&R Cover Page	Form	Pages 1 & 2.	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.
SF-424 R&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-424 R&R 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. See Biographical Sketch format in Appendix A.
Senior Key Personnel Current and Pending Support	Attachment	Can be uploaded in SF-424 R&R Senior/Key Person Profile form.	Not Applicable to HRSA. Do not use.
Additional Senior/Key Person Profiles	Attachment	Can be uploaded in SF-424 R&R Senior/Key Person Profile form. Single document with all additional profiles.	Counted in the page limit.
Additional Senior Key Personnel Biographical Sketches	Attachment	Can be uploaded in the Senior/Key Person Profile form. Single document with all additional sketches.	Counted in the page limit. See Biographical Sketch format in Appendix A
Additional Senior Key Personnel Current and Pending Support	Attachment	Can be uploaded in the Senior/Key Person Profile form.	Not Applicable to HRSA. Do not use.

Application Section	Form Type	Instruction	HRSA/Program Guidelines
Project/Performance Site Location(s)	Form	Supports primary and 29 additional sites in structured form.	Not counted in the page limit.
Additional Performance Site Location(s)	Attachment	Can be uploaded in SF-424 R&R Performance Site Location(s) form. Single document with all additional site location(s).	Counted in the page limit.
Other Project Information	Form	Allows additional information and attachments.	Not counted in the page limit.
Project Summary/Abstract	Attachment	Can be uploaded in SF-424 R&R Other Project Information form, Box 7.	Required attachment. Counted in the page limit. Refer to Section 4.1ix of this Guide and the FOA for detailed instructions.
Project Narrative	Attachment	Can be uploaded in SF-424 R&R Other Project Information form, Box 8.	Required attachment. Counted in the page limit. Refer to the FOA for detailed instructions. If necessary provide table of contents specific to this document only as the first page. Table of contents is not counted in the page limit.
Bibliography & References Cited	Attachment	Can be uploaded in SF-424 R&R Other Project Information form, Box 9.	If this attachment is required, it will be counted in the page limit. Please refer to the FOA.
Facilities & Other Resources	Attachment	Can be uploaded in SF-424 R&R Other Project Information form, Box 10.	If this attachment is required, it will be counted in the page limit. Please refer to the FOA.
Equipment	Attachment	Can be uploaded in SF-424 R&R Other Project Information form, Box 11.	If this form is required, it will be counted in the page limit. Please refer to the FOA.
Other Attachments	Attachment	Can be uploaded in SF-424 R&R Other Project Information form, Box 12. Supports multiple.	Not Applicable to HRSA. Do not use.
SF-424 R&R Budget Period (1-5) - Section A – B	Form	Supports structured budget for up to 5 periods.	Not counted in the page limit.

Application Section	Form Type	Instruction	HRSA/Program Guidelines
Additional Senior Key Persons	Attachment	SF-424 R&R Budget Period (1-5) - Section A - B, End of Section A. One for each budget period.	Counted in the page limit.
SF-424 R&R Budget Period (1-5) - Section C – E	Form	Supports structured budget for up to 5 periods.	Not counted in the page limit.
Additional Equipment	Attachment	SF-424 R&R Budget Period (1-5) - Section C – E, End of Section C. One for each budget period.	Counted in the page limit.
SF-424 R&R Budget Period (1-5) - Section F – K	Form	Supports structured budget for up to 5 periods.	Not counted in the page limit.
Budget Justification	Attachment	Can be uploaded in SF-424 R&R Budget Period (1-5) - Section F - K form, Box K. Only one consolidated budget justification for the project period.	Required attachment. Counted in the page limit. Refer to Section 4.1.v of this Guide and the FOA for detailed instructions. Provide table of contents specific to this document only as the first page.
SF-424 R&R Cumulative Budget	Form	Total cumulative budget.	Not counted in the page limit.
SF-424 R&R Subaward Budget Attachment(s) Form	Form	Supports up to 10 budget attachments. This form only contains the attachment list.	Not counted in the page limit.
Research and Related Budget- Subaward Budget Form	Extracted Form	Access this form by clicking on “Click here to extract the R&R Subaward Budget Attachment,” then save this PDF form, complete, and attach to the SF 424 R&R Subaward Budget Attachment(s) Form.	Filename should be the name of the organization and unique. The extracted form will not count toward the page limit, however, any budget narratives or other attachments to the SF 424 R&R Subaward Budget Attachment(s) Form will count.
SF-424B Assurances for Non-Construction Programs	Form	Assurances for the SF-424 R&R package.	Not counted in the page limit.
Disclosure of Lobbying Activities (SF-LLL)	Form	Supports structured data for lobbying activities.	Not counted in the page limit.

Application Section	Form Type	Instruction	HRSA/Program Guidelines
Attachments Form	Form	Supports up to 15 numbered attachments. This form only contains the attachment list.	Not counted in the page limit.
Attachments 1-15	Attachment	Can be uploaded in Other Attachments form 1-15.	Refer to the attachment table provided below for **specific** sequence. Counted in the page limit.

- To ensure that attachments are organized and printed in a consistent manner, follow the order provided in the FOA. Note that these instructions may vary across programs.
- Evidence of Non-Profit status and invention-related documents, if applicable, must be provided in the other attachment form (not counted in the page limit).
- 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 FOA.
- Merge similar documents into a single document. Where several documents are expected in one attachment, ensure that a table of contents cover page is included specific to the attachment. The Table of Contents page will not be counted in the page limit.

Attachment Number	Attachment Description (Program Guidelines)
Attachments 1-15	Please see instructions in the FOA

4.4. Application Page Limit

The total size of all uploaded files may not exceed the page limit specified in Section IV. 2 of the FOA when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the FOA. Standard OMB-approved forms included in the application package, an organization's approved Indirect Cost Rate Agreement, and proof of non-profit status are NOT included in the page limit. All other documents will count toward the page limit, unless noted in the FOA. **We strongly urge you to take appropriate measures to ensure the application does not exceed the specified page limit.**

Applications must be complete, within the specified page limit, and validated under the correct funding opportunity number prior to the deadline to be considered under the announcement.

You must follow the instructions provided in this section. HRSA recommends that you print out all attachments and confirm the number of pages before submission.

- **NOTE: Applications that exceed the specified limits or are submitted under the wrong announcement number will be deemed non-responsive, will not be considered for award and the applicants will be notified.**

4.5. Submission Dates and Times

Notification of Intent to Apply (ONLY if requested in FOA on cover and in Section IV.7.)
You are eligible to apply even if no letter of intent is submitted. The letter should identify your organization and its intent to apply, and briefly describe the proposal to be submitted. Receipt of Letters of Intent will *not* be acknowledged.

This letter should be sent via email by *the date listed in FOA,* to:

HRSA Digital Services Operation (DSO)
Please use HRSA opportunity number as email subject (HRSA-XX-XXX)
HRSADSO@hrsa.gov

Application Due Date
The due date for applications is *11:59 P.M. Eastern Time* on the date listed in Section IV.4. Submission Dates and Times in the FOA, unless otherwise noted. Applications completed online are considered formally submitted when the application has been successfully transmitted electronically to the correct FOA number, by the organization's AOR through Grants.gov and validated by Grants.gov under the correct funding opportunity number on or before the deadline date and time.

4.6. Correcting Mistakes

If, for any reason (including submitting to the wrong funding opportunity number), an application is submitted more than once prior to the application due date, HRSA will only accept your last validated electronic submission, under the correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application. If you need to correct a Grants.gov application mistake, **in Box 1 of the SF-424 R&R, check "Changed/Corrected Application,"** and submit the corrected version before the application deadline.

It is incumbent on you to ensure that the AOR is available to submit the application to HRSA by the published due date. HRSA will not accept submission or re-submission of incomplete, rejected, or otherwise delayed applications after the deadline. Therefore, you are urged to submit your application in advance of the deadline. If an application is rejected by Grants.gov due to errors, it must be corrected and resubmitted to Grants.gov before the deadline date and time. Deadline extensions will not be provided to applicants who do not correct errors and resubmit before the posted deadline.

4.7. Tips for Writing a Strong Application

HRSA has designed a TA webpage to assist you in preparing your application. Resources include help with system registration, finding and applying for funding opportunities, writing strong applications, understanding the review process, and many other topics which you will find relevant. The website can be accessed at: http://www.hrsa.gov/grants/apply/index.html.

In addition, a concise resource offering tips for writing proposals for HHS grants and cooperative agreements can be accessed at: http://www.hhs.gov/asfr/ogapa/aboutog/apptips.html.

4.8. Withdrawing an Application

You may withdraw your application from consideration at any time before an award is issued. Notification of this withdrawal should be sent via email to DGPWaivers@hrsa.gov, with a copy sent to the PC and GMS listed in the FOA.

5. PROCESS OVERVIEW

5.1. Competing Applications Through Grants.gov

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

1) HRSA will post all competing FOAs on Grants.gov (http://www.grants.gov).
2) In order to apply for a HRSA grant, you must complete the Grants.gov registration process. See Section 4 for more details.
3) Once the FOA is available, you should search for the announcement in Grants.gov by clicking the SEARCH GRANTS tab (http://www.grants.gov/web/grants/search-grants.html), entering the FOA number (HRSA-1X-XXX) and then selecting the announcement. Or by clicking the APPLICANTS tab under *Apply for Grants* (http://www.grants.gov/web/grants/applicants/apply-for-grants.html).
4) Download the application package and instructions from Grants.gov. The FOA, accessible via the instructions link, contains critical application instructions and must be downloaded. Make note of the Announcement Number.
5) Save a copy of the application package on your computer, or to a location you choose and complete all the forms based on the instructions provided in the FOA.
6) Submit the application package through Grants.gov (requires registration – see Section 4).
7) Track the status of your submitted application using Track My Application at Grants.gov until you receive email notifications that your application has been received **and** validated by Grants.gov and received by HRSA. Be sure the application was validated under the correct funding opportunity number.
8) Once your application has been validated by Grants.gov, you may track the status of the application within HRSA by using the "Track Your Application" widget, now available on HRSA's website at http://www.hrsa.gov/grants/index.html. The application tracker will let you know where your application is at every stage in the process.

5.2. Application Processing

HRSA staff review each application for eligibility, responsiveness, completeness, and conformity with the requirements outlined in the relevant FOA, including programmatic, budgetary, and grants management compliance. 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 Section V. 1. Review Criteria of the relevant FOA.

All incomplete applications, ineligible, or otherwise non-compliant applications, and applications determined to be non-responsive to FOA requirements will not be considered for funding. You may withdraw your application from consideration at any time before an award is issued.

For those applications that did not pass the initial screening, applicants will be advised by letter (sent to the individual signing the application on behalf of the organization) that the application will not be held for further consideration or be funded. The decision not to make an award or to make an award at a particular funding level, is discretionary and is not subject to appeal to any OPDIV or HHS official or board.

5.3. Objective Review Information

The Division of Independent Review is responsible for managing objective reviews within HRSA. The objective review provides advice to the individual responsible for making award decisions. Objective review is essential to ensuring selection of applications that best meet the needs of the program consistent with published evaluation criteria and providing assurance to the public that the evaluation process is impartial and fair. 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 presented in Section V. 1. Review Criteria of the FOA.

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 the FOA. 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.

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist you in understanding the standards against which each application will be judged. Critical indicators have been developed for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. Review criteria found in the FOAs are outlined with specific detail and scoring points.

Funding factors may be applied during the objective review process or in the selection process. Funding factors are addressed in the FOA, which will specify if you must make an affirmative request to be considered for a funding factor, what information is needed to demonstrate eligibility for the funding factor, and whether objective reviewers determine if you've met the funding factor. The announcement provides a detailed explanation of preferences, priorities, or special considerations with an explicit indication of their effect (e.g., whether they result in additional points being assigned). It is HRSA

policy that funding preferences, priorities, and special considerations must be published in the FOA.

You will receive written notification of the outcome of the objective review process, including a summary of the expert committee's assessment of the application's strengths and weaknesses, and whether the application was selected for funding.

5.4. Award Notification

The Notice of Award (NoA) is the legal document issued to the recipient that indicates an award has been made and that funds may be requested from HRSA. Until an awarding office has issued an NoA for the initial budget period, any costs incurred by the applicant for the project are incurred at its own risk. HRSA may reimburse pre-award costs only to the extent that they would otherwise be allowable. The NoA sets forth the amount of funds granted, the terms and conditions of the award, the effective date of the award, the budget period for which initial support will be given, the non-federal share to be provided (if applicable), and the total project period for which support is contemplated. Signed by the Grants Management Officer (GMO), it is sent to the applicant's Authorized Organization Representative (AOR), and reflects the only authorizing document. Any other correspondence announcing that an application has been selected for award is not an authorization to begin performance. Generally, it will be sent prior to the start date of the award as listed in Section V.4 of the FOA.

A revised NoA may be issued during a budget period to effect an action resulting in a change in the period or amount of support or other change in the terms and conditions of award. An awarding office generally will not issue a revised NoA to reflect a recipient's post-award rebudgeting. Applicants who are selected for funding may be required to respond in a satisfactory manner to conditions placed on their award document before funding can proceed. Letters of notification do not provide authorization to begin performance.

Unsuccessful applicants will receive notification from HRSA's Division of Grants Management Operations.

6. REPORTING REQUIREMENTS

Successful applicants generally must comply with the following standard reporting and review activities, unless otherwise noted in the FOA or NoA. Some programs require program-specific reporting, please see Section VI. 3. Reporting in the FOA.

a. Audit Requirements
Comply with audit requirements of 45 CFR 75, Subpart F. Information on audits can be found on the Internet at http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4d52364ec83fab994c665943dadf9cf7&ty=HTML&

h=L&r=PART&n=pt45.1.75#sp45.1.75.f.

b. Payment Management Requirements

If applicable, the awardee must submit a quarterly electronic Federal Financial Report (FFR) Cash Transaction Report via the Payment Management System (PMS). The report identifies cash expenditures against the authorized funds for the grant or cooperative agreement. The FFR Cash Transaction Reports must be filed within 30 days of the end of each calendar quarter. Failure to submit the report may result in the inability to access award funds. Go to http://www.dpm.psc.gov for additional information.

c. Status Reports

1) **Federal Financial Report**. The Federal Financial Report (SF-425) is required according to the following schedule: http://www.hrsa.gov/grants/manage/technicalassistance/federalfinancialreport/ffrschedule.pdf. The report is an accounting of expenditures under the project that year. Financial reports must be submitted electronically through HRSA EHBs. More specific information will be included in the NoA.

2) **Progress Report**(s). The awardee must submit a progress report to HRSA on a quarterly, semi-annual, or annual basis (as specified in the FOA). For multi-year awards: Submission and HRSA approval of awardee Progress Report(s) triggers the budget period renewal and release of subsequent year funds. This report has two parts. The first part demonstrates awardee progress on program-specific goals. The second part collects core performance measurement data including performance measurement data to measure the progress and impact of the project. Further information will be provided in the NoA.

3) **Final Report.** A final report is due within 90 days after the project period ends. The final report collects information relevant to program-specific goals and progress on strategies; core performance measurement data; impact of the overall project; the degree to which the awardee achieved the mission, goal and strategies outlined in the program; awardee objectives and accomplishments; barriers encountered; and responses to summary questions regarding the awardee's overall experiences during the entire project period. The final report must be submitted online by awardees in the HRSA EHBs system at https://grants.hrsa.gov/grantee.

4) **Tangible Personal Property Report.** If applicable, the awardee must submit the Tangible Personal Property Report (SF-428) and any related forms. The report must be submitted within 90 days after the project period ends. Awardees are required to report all federally-owned property and acquired equipment with an acquisition cost of $5,000 or more per unit. Tangible personal property means property of any kind, except real property, that has physical existence. It includes equipment and supplies. Property may be provided by HRSA or acquired by the recipient with award funds. Federally-owned property consists of

items that were furnished by the Federal Government. Tangible personal property reports must be submitted electronically through HRSA EHBs. More specific information will be included in the NoA.

5) **Any other required reports and/or products specified in the FOA**.

d. Transparency Act Reporting Requirements
New awards ("Type 1") issued are subject to the reporting requirements of the Federal Funding Accountability and Transparency Act (FFATA) of 2006 (P. L. 109–282), as amended by section 6202 of P.L. 110–252, and implemented by 2 CFR part 170. IMPORTANT: The reporting requirements apply for the duration of the project period and so include all subsequent award actions to aforementioned HRSA grants and cooperative agreement awards (e.g., Type 2 (competing continuation), Type 5 (non-competing continuation), etc.). Grant and cooperative agreement recipients must report information for each first-tier subaward of $25,000 or more in federal funds and executive total compensation for the recipient's and subrecipient's five most highly compensated executives as outlined in Appendix A to 2 CFR part 170 (FFATA details are available online at http://www.hrsa.gov/grants/ffata.html).

7. AGENCY CONTACTS

7.1. Working with HRSA Program and Grants Management Staff

For assistance with overall program-related questions, contact the PC listed in Section VII. Agency Contacts of the FOA.

For additional information regarding business, administrative, or fiscal issues, contact the GMS listed in Section VII. Agency Contacts of the FOA. The PC and the GMS work as a team in many award-related activities.

Please contact Grants.gov Customer Support for technical questions related to Grants.gov.

7.2. Grants.gov Customer Support

Direct all questions regarding Grants.gov to the Grants.gov Call Center at: 1-800-518-4726 (International callers, please dial 606-545-5035) or via email at support@grants.gov. Call Center hours of operation are 24 hours a day, 7 days a week, excluding federal holidays. Please be sure to obtain a case number every time you call so that your issue can be tracked.

For additional support with the Grants.gov Web site, visit http://www.grants.gov/web/grants/support.html. You can also visit the Grants.gov Self-

Service Knowledge Base for answers to commonly asked questions (https://grants-portal.psc.gov/Welcome.aspx).

8. FAQS AND OTHER INFORMATION

8.1. Software FAQs

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

You will need to download Adobe Reader. For information on Adobe Reader, go to http://www.grants.gov/web/grants/support/technical-support/recommended-software.htm.

8.1.2. Adobe Reader

The Adobe Reader screen is shown in **Adobe Reader Screen** below.

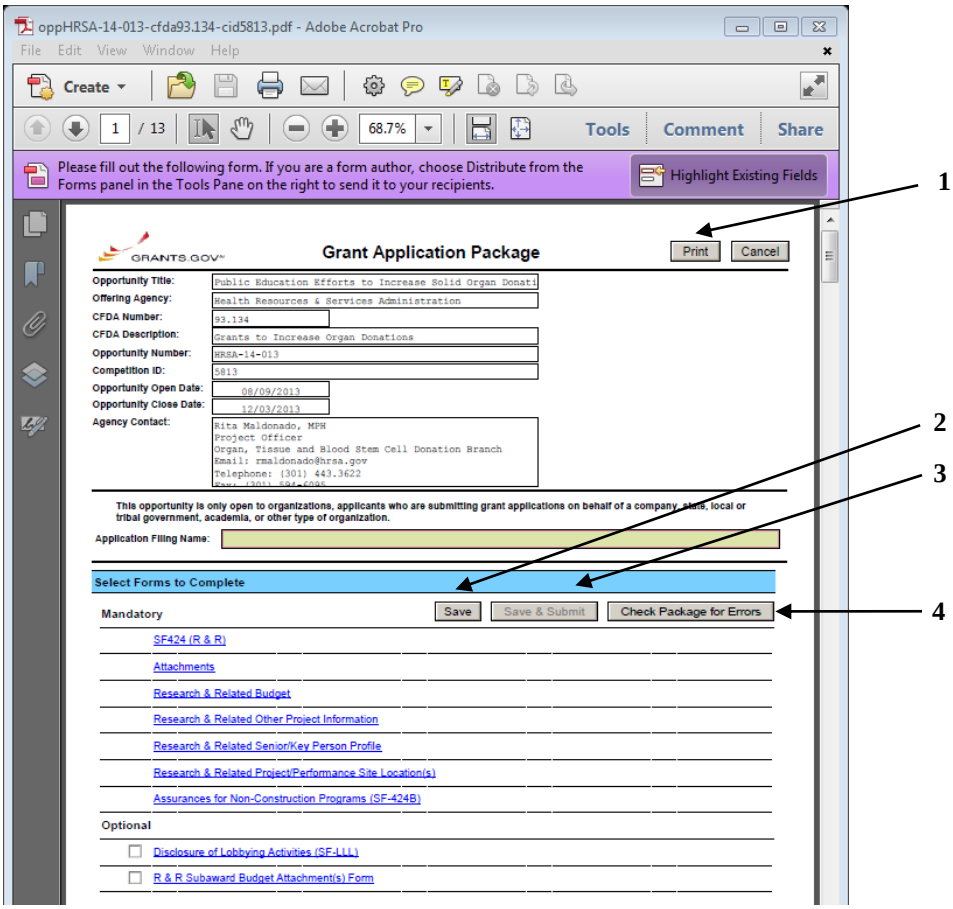

Figure 1: The Adobe Reader Toolbar

1. Print – Click to print the application package.
2. Save – Click to save the application package to your local computer.
3. Save & Submit – Click to submit the application package to Grants.gov. (The **Save & Submit** button on the application package cover page will only become active after you have completed all required forms, attached all required documents, saved your application package, and your package is free from errors.)
4. Check Package for Errors – Click prior to submitting the application package to ensure there are no errors.

Open and complete all of the documents listed under **Mandatory Documents**, as well as the relevant documents under **Optional Documents**. Refer to **Figure 2** below.

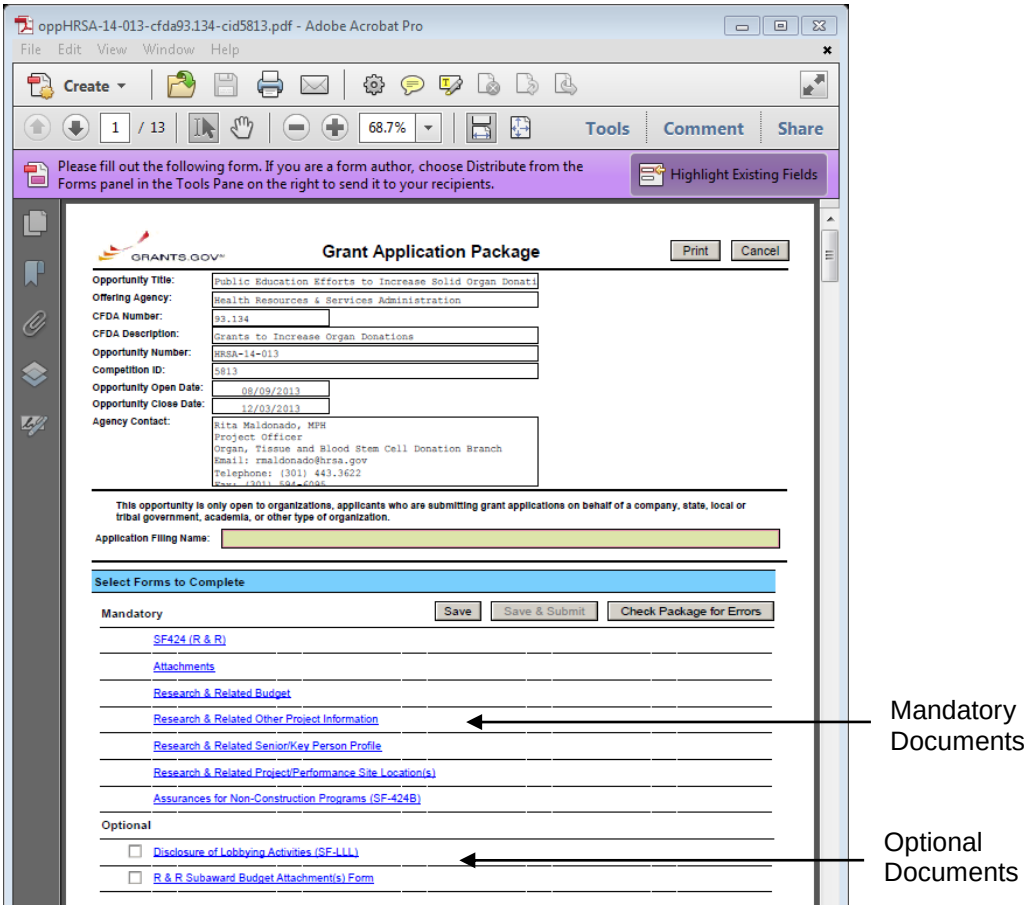

Figure 2: Working with Mandatory and Optional Documents (Adobe Reader)

1. The documents listed under Mandatory Documents and Optional Documents may be predefined forms, such as SF-424, or documents that need to be attached, such as a staffing plan and job descriptions for key personnel. Mandatory Documents are required for this application. Optional Documents can be used to provide additional support for this application or may be required for

specific types of award activity. Reference the FOA for more information regarding Optional Documents.

2. To open a form, click on the form name. It will jump to the first page of the form. For Optional forms, tick first the box on the left of the form name.

3. To remove an optional form, unselect the box on the left of the form name.

4. When you open a required form, the fields which must be completed are noted by an asterisk and highlighted in yellow with a red border. Optional fields and completed fields are displayed in white. If you enter invalid or incomplete information in a field, you will receive an error message.

5. To exit a form within the application, select the **Close Form** button at the top of the form you are filling out. Then to save your work, select the **Save** button (on the cover page) to save your entire application.

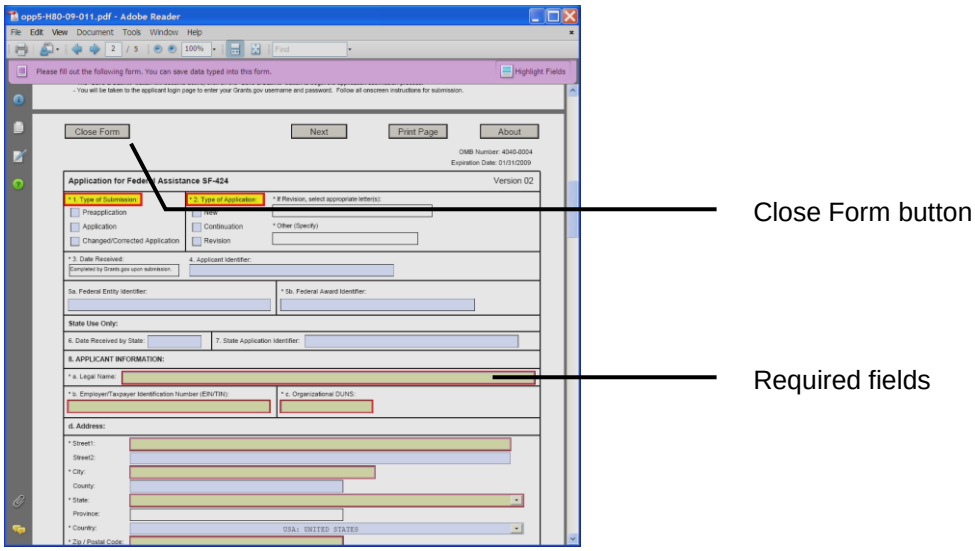

Figure 3: An Open Form in Adobe Reader

Note that the buttons are attached to the top of the page and move with the page. Click on the *Close Form* button to save and close the form. Refer to **Figure 3** above.

Special Note: Working with Earlier Versions of Adobe Reader
It is highly recommended that you remove all earlier versions of Adobe Reader prior to installing the latest version of Adobe Reader. Do this by using *Add or Remove Programs* from the Control Panel in Windows.

If you need to keep older versions of Adobe Reader on your computer, you should be aware that the program will unsuccessfully attempt to open application packages with the earlier, incompatible version. Use the following workaround to avoid this problem.

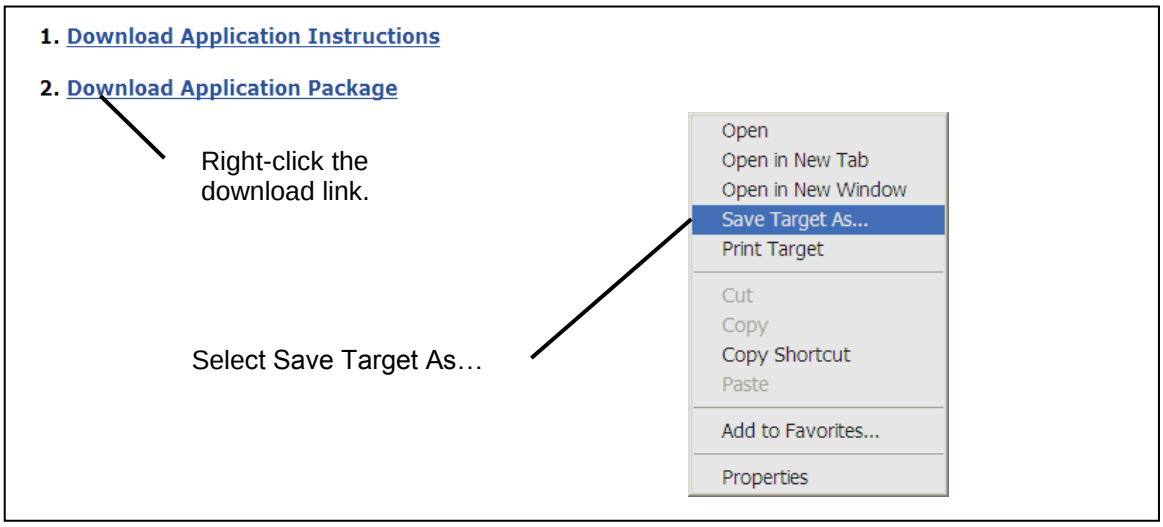

Figure 4: Downloading from Grants.gov

1. From the Grants.gov download page, right-click on the *Download Application Package* link and select **Save Target As**… from the menu.
2. Save the target on your computer (preferably to the Desktop) as an Adobe Acrobat Document.

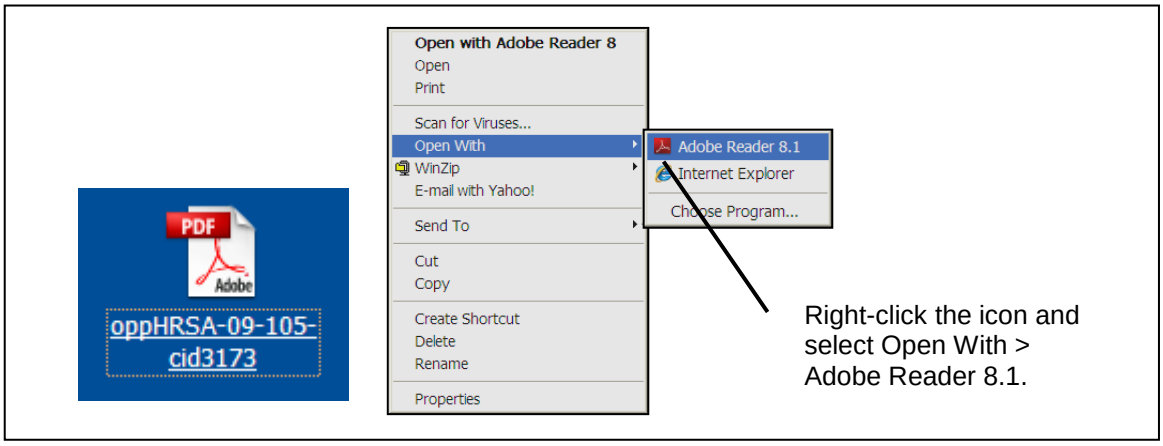

Figure 5: Selecting Open with Adobe Reader

3. Right-click the icon.
4. Select *Open With* > *Adobe Reader 8.1* from the menu.

8.1.3. Can I download Adobe Reader onto my computer?

There are software applications that allow you to successfully navigate the Grants.gov pages and complete your application. These applications can be found at http://www.grants.gov/web/grants/support/technical-support/recommended-software.html. However, depending on your organization's computer network and security protocols you may **not** have the necessary permissions to download software onto your workstation. Contact your IT department or system administrator to download the software for you or give you access to this function.

8.1.4. Is Grants.gov Macintosh (Mac) compatible?

Yes, visit http://www.grants.gov/web/grants/support/technical-support/recommended-software.html.

8.2. Application Receipt FAQs

8.2.1. When do I need to submit my application?

Generally, applications must be submitted to Grants.gov by 11:59 p.m. Eastern Time on the due date, however the time may vary. You should refer to the FOA for exact submission dates and times. An application for HRSA funding must be both received **and** validated by Grants.gov under the correct funding opportunity number by the application deadline.

8.2.2. What is the receipt date (the date the application is electronically received by Grants.gov or the date the data is received by HRSA)?

The submission/receipt date is the date the application is electronically received and validated by Grants.gov. An application for HRSA funding must be both received **and** validated under the correct funding opportunity number by Grants.gov by the application deadline. Please allow sufficient time to have the application validated, which can take up to 48 hours.

8.2.3. Once my application is submitted, how can I track my application and what emails can I expect from Grants.gov and HRSA?

You can check the status of your application any time after submission by logging into Grants.gov and clicking on the *Track My Application* link. This link will also be included in the confirmation email that you receive from Grants.gov.

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

The first will confirm receipt of your application by the Grants.gov system ("Received"). 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"). An application for HRSA funding must

be both received **and** validated under the correct funding opportunity number by Grants.gov by the application deadline.

Subsequently, the application will be downloaded by HRSA upon successful validation of your application by Grants.gov. The status of the application will then change to "Received by Agency" after successful validation and you will receive a third email from Grants.gov.

HRSA will process the application to ensure that it has been submitted for the correct funding announcement number, along with the correct grant number (if applicable) and awardee/applicant organization. This may take up to three business days. HRSA will assign a unique tracking number to your application which will be posted to Grants.gov. The status of your application will then be changed to "Agency Tracking Number Assigned" and you will receive a fourth email from Grants.gov.

- **NOTE:** Refer to FAQ 8.2.5 below for a summary of emails.

8.2.4. If a resubmission is required due to technological problems encountered using the Grants.gov system and the closing date has passed, what should I do?

You must **contact the Director of the Division of Grants Policy at HRSA**, within five calendar days from the closing date, via email at DGPWaivers@hrsa.gov and provide a detailed explanation. Your email must include the HRSA Announcement Number, the name, address, and telephone number of the Organization, the organization's DUNS number, and the Name and telephone number of the Project Director, as well as the Grants.gov Tracking Number (GRANTXXXXXXXX) assigned to your submission, along with a copy of the "Rejected with Errors" notification you received from Grants.gov. Extensions for funding opportunity deadlines are only granted in the rare event of a natural disaster or validated technical system problem on the side of the Government that prevented a timely application submission. An application for HRSA funding must be both received **and** validated under the correct funding opportunity number by the application deadline.

8.2.5. Can you summarize the emails received from Grants.gov and identify who will receive the emails?

Submission Type	Subject	Timeframe	Sent By	Recipient
Competing Application	"Submission Receipt"	Within 48 hours	Grants.gov	AOR
	"Submission Validation Receipt" OR "Rejected with Errors"	Within 48 hours	Grants.gov	AOR
	"Grantor Agency Retrieval Receipt"	Within hours of second email	Grants.gov	AOR

Submission Type	Subject	Timeframe	Sent By	Recipient
	"Agency Tracking Number Assignment"	Within three business days	Grants.gov	AOR

8.3. Application Submission FAQ

8.3.1. How can I make sure that my electronic application is presented in the correct order for objective review?

Follow the instructions provided in Section 4 to ensure that your application is presented in the correct order and is compliant with all the requirements.

8.4. Grants.gov FAQs

For a list of frequently asked questions and answers maintained by Grants.gov, please visit http://www.grants.gov/web/grants/support/general-support/faqs.htm

Grants.gov offers several tools and numerous user guides to assist applicants that are interested in applying for grant funds. To view the many applicant resources available through Grants.gov please visit http://www.grants.gov/web/grants/applicants/applicant-resources.htm.

8.5. Application Completeness Checklist

- ❑ Have I read the FOA and this *SF-424 R&R Application Guide* thoroughly?
- ❑ Is my organization eligible to apply for this announcement?
- ❑ Am I applying to the correct funding opportunity number?
- ❑ Is my proposed project responsive to the stated goals and objectives of the program as specified in the FOA?
- ❑ Have I ensured my application does not exceed the ceiling amount specified in Section III of the FOA?
- ❑ Have I completed all forms and attachments as requested in Section IV of the FOA and this *Guide*?
- ❑ Have I taken the appropriate measures to ensure my application does not exceed the page limit specified in the FOA?
- ❑ Will I apply at least three days prior to the deadline to accommodate any unforeseen circumstances?
- ❑ Have I received confirmation emails from Grants.gov noting validation of successful submission?

8.6. Program Specific Resources and Technical Assistance

For additional information/resources, refer to Section VIII. Other Information in the FOA. This section may include TA calls (if scheduled), related programs, useful website addresses, etc.

9. TECHNICAL ASSISTANCE RESOURCES

HRSA has developed the How to Apply for a Grant TA webpage at http://www.hrsa.gov/grants/apply. This is a one-stop shop for potential applicants on how to apply for HRSA funding. You will find valuable information on how to apply for HRSA awards, including webcasts, videos, and other technical assistance guidance.

APPENDIX A - BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES (*Refer to FOA for exact limit*). Counted in the page limit.**

NAME:

POSITION TITLE:

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY

Please refer to the instructions in Section 4.1.vi Staffing Plan and Personnel Requirements of this Guide in order to complete sections A, B, C, and D of the Biographical Sketch.

Public reporting burden for this collection of information is estimated to average two hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. ***An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*** *Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857. Do not return the completed form to this address.*

APPENDIX B: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan

1. Introduction

A Protection of Human Subjects section of the Research Plan is required for certain applications submitted using the SF-424 R&R instructions and forms. The information provided in the section on Protection of Human Subjects should be consistent with the information provided on the face page of the application.

For all research involving human subjects, the Scientific Review Group (SRG) will assess the adequacy of protections for research participants against research risks, and the appropriate inclusion of women, minorities, and children, based on the information provided in the application.

To assist in preparing the section on Protection of Human Subjects, five possible scenarios are provided in Section 2 below. All research projects will fall into one of these five. Determine which scenario the proposed research falls into, then go to the specific instructions applicable to that scenario in Section 3. Where appropriate, Section 3 provides instructions on addressing the Inclusion of Women and Minorities, information on Targeted/Planned Enrollment, and the Inclusion of Children (items 7, 8, and 9 of the Research Plan). Section 5 of this Part includes descriptions of and links to the HHS Human Subjects Protections regulations.

Do not use the human subjects section to circumvent the page limit of the Research Strategy.

NOTE: Clinical trials/research is allowable only if the statutory authority permits. Please consult the FOA.

2. Scenarios

Scenario A. No Human Subjects Research
If no human subjects research is proposed in the application, you will have designated **No** in Item 1 on the SF-424 R&R Other Project Information page. If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

See the instructions for Scenario A.

Unless you are providing a special justification as described above, no additional information is necessary if no human subjects are involved.

Scenario B. Non-Exempt Human Subjects Research
If research involving human subjects is anticipated to take place under the award, you will have designated **Yes** in Item 1 on the SF-424 R&R Other Project Information page and entered your Human Subject Assurance Number (per RESEARCH & RELATED Other Project Information page) in Item 1a. In the Protection of Human Subjects section of the Research Plan, you must provide sufficient information for reviewers to determine that the proposed research meets (1) the requirements of the HHS regulations to protect human subjects from research risks (45 CFR part 46), and (2) the requirements of PHS policies on inclusion of women, minorities, and children.

See the instructions for Scenario B.

Scenario C. Exempt Human Subjects Research
If **all** of the proposed human subjects research meets the criteria for one or more of the exemptions from the requirements in the HHS regulations (46.101(b)), **Yes** should be designated in Item 1 on the SF-424 R&R Other Project Information page, the appropriate exemption number checked in Item 1a, and "NA" entered for the Human Subject Assurance Number since no assurance number is required for exempt research. In the section on Protection of Human Subjects in the Research Plan, provide a justification for the exemption(s) containing sufficient information about the involvement of the human subjects to allow a determination by objective reviewers and HRSA staff that claimed exemption(s) is/are appropriate.

The PHS will make a final determination as to whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the Research Plan. When in doubt, consult with the Office for Human Research Protections (OHRP), Department of Health and Human Services by accessing their Web site http://www.hhs.gov/ohrp/ for guidance and further information.

The six categories of research exempt from the HHS human subjects regulations are found at the end of this document.

Please note: If the proposed research involves only the use of human data or biological specimens, you should first determine whether the research involves human subjects. The exemptions do not apply if the research does not involve human subjects.

See the instructions for Scenario C.

Scenario D. Delayed-Onset Human Subjects Research
If human subjects research is anticipated within the period of the award but plans for involvement of human subjects cannot be described in the application as allowed by the HHS regulations (45 CFR part 46.118), you will have designated **Yes** in Item 1 on the SF-424 R&R Other Project Information page and entered your Human Subject Assurance Number in Item 1a. In the section on Protection of Human Subjects in the Research Plan, you should either include an explanation of anticipated protections for

human subjects or an explanation of why protections cannot be described. Examples of delayed-onset of human subjects research include:

- Human subjects research is dependent upon the completion of animal or other studies; or
- Human subjects research protocols to be included will undergo an independent decision-making process (often defined by a FOA).

See instructions for Scenario D.

Scenario E. Human Subjects Research Involving a Clinical Trial
If research involving human subjects is anticipated to take place under the award, and you intend to conduct a clinical trial during the project period, you will have designated **Yes** in Item 1 on the SF-424 R&R Other Project Information page, entered your Human Subject Assurance Number in Item 1a. In the section on Protection of Human Subjects in the Research Plan, you must provide sufficient information for reviewers to determine that the proposed research meets:

1) the requirements of the HHS regulations to protect human subjects from research risks (45 CFR part 46);
2) PHS policy requirements for Data and Safety Monitoring for Clinical Trials;
3) the ClinicalTrials.gov requirements if applicable;
4) the requirements of PHS policies on inclusion of women, minorities, and children; and
5) the requirements of PHS policy on reporting race and ethnicity data for human subjects in clinical research.

See instructions for Scenario E.

3. Instructions for Preparing the Section on Protection of Human Subjects

Scenario A. No Human Subjects Research Proposed

Criteria

Human Subjects Research	No
Exemption Claimed	No
Clinical Trial	N/A

Instructions and Required Information

If proposed studies using human data or biological specimens do not involve human subjects as described in the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens (http://www.hhs.gov/ohrp/policy/cdebiol.html), provide an explanation of why the proposed studies do not constitute research involving human subjects.

The explanation could include: a description of the source of the data/biological specimens, and whether there is any intervention or interaction with the subjects in order to obtain the specimens and data; what identifiers will be associated; the role(s) of providers of the data/biological specimens in the proposed research; and the manner by which the privacy of research participants and confidentiality of data will be protected.

Research that does not involve intervention or interaction with living individuals, or identifiable private information, is not human subjects research. Research involving the use of coded private information or biological specimens may not constitute human subjects research if the conditions of the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens have been met (http://www.hhs.gov/ohrp/policy/cdebiol.html).

Research that only proposes the use of cadaver specimens is not human subjects research because human subjects are defined as "living individuals." The use of cadaver specimens is not regulated by 45 CFR part 46, but may be governed by other federal, state or local laws.

Scenario B. Non-Exempt Human Subjects Research

Criteria

Human Subjects Research	Yes
Exemption Claimed	No
Clinical Trial	No

Instructions and Required Information

Although no specific page limitation applies to this section of the application, be succinct. In the application narrative, provide the required information for each of the following topics below:

- Protections of Human Subjects - Section 4.1 - 4.1.4
- Inclusion of Women and Minorities - Section 4.2
- Targeted/Planned Enrollment - Section 4.3
- Inclusion of Children - Section 4.4

If the research involves collaborating sites or subprojects, provide the information identified above for each participating site.

Scenario C: Human Subjects Research Claiming Exemption 1, 2, 3, 4, 5, or 6

Criteria

Human Subjects Research	Yes
Exemption Claimed	1, 2, 3, 4, 5, or 6
Clinical Trial	Yes or No

Instructions and Required Information
Although no specific page limitation applies to this section of the application, be succinct. The six categories of research exempt from the HHS human subjects regulations are found at the end of this document.

Although the research may be exempt from the HHS regulatory requirements, it is still research involving human subjects and the application must follow the instructions that are identified for each of the following topics and provide the information that is requested.

In the application narrative, provide the required information for each of the following topics below:

- Protections for Human Subjects – Include the following statement: 'This Human Subjects Research falls under Exemption(s) … .' Clearly identify which exemption(s) (1, 2, 3, 4*, 5, 6) you are claiming, and justify why the research meets the criteria for exemption that you have claimed. If the research will include a clinical trial, even if exempt, include a Data and Safety Monitoring Plan – Section 4.1.5, and address the ClinicalTrials.gov requirements if applicable – Section 4.1.6.
- Inclusion of Women and Minorities - Section 4.2
- Targeted/Planned Enrollment - Section 4.3
- Inclusion of Children - Section 4.4

*NOTE: If all the proposed research meets the criteria for Exemption 4, then the requirements for inclusion of women and minorities, targeted/planned enrollment table, and inclusion of children, do not need to be addressed.

Scenario D: Delayed-Onset Human Subjects Research

Criteria

Human Subjects Research	Yes
Exemption	Yes or No
Clinical Trial	Yes or No

Instructions and Required Information

In rare situations, applications are submitted with the knowledge that human subjects will be involved during the period of support, but plans are so indefinite that it is not possible to describe the involvement of human subjects in the application. The kinds of activities that lack definite plans are often institutional awards where the selection of specific projects is the institution's responsibility, research training grants, and projects in which the involvement of human subjects depends upon completion of instruments, animal studies, or purification of compounds.

If the involvement of human subjects cannot be fully described, create a heading entitled “Protection of Human Subjects” and provide a detailed explanation why it is not possible to develop definite plans at this time. The explanation should be specific and directly related to the Specific Aims in the application. If the involvement of human subjects depends upon information that is not presently available (e.g., completion of instruments, animal studies, purification of compounds), be explicit about the information and the factors affecting the availability of the information. Describe the information that will be necessary in order to develop definite plans for the involvement of human subjects, why that information is not currently available, and when the information is expected to become available during the course of the project.

If an award is made, prior to the involvement of human subjects the awardee must submit to the HRSA awarding office for prior approval either (1) detailed information as required in the Research Plan, Protection of Human Subjects (addressing risks to the subjects, adequacy of protection against risks, potential benefits of the proposed research, importance of the knowledge to be gained, and data and safety monitoring plan if applicable) and certification of IRB approval, OR (2) if all of the research meets the criteria for one or more exemptions, identification of which exemption(s) is/are applicable to the research, and a justification for the exemption with sufficient information about the involvement of human subjects to allow a determination that the claimed exemption is appropriate. For clinical research, the request for prior approval must also address the inclusion of women and minorities, the inclusion of children, and provide completed targeted/planned enrollment tables as required in the Research Plan.

Under no circumstance may human subjects be involved in research until approval is granted by the awarding entity, and certification of IRB approval has been accepted by the agency.

In the application narrative, provide the required information for each of the following topics below. Follow the instructions that are identified for each of the following topics and EITHER provide as much of the information that is requested as possible; OR describe why it is not possible to provide the information due to delayed-onset of human subjects research:

- Protection of Human Subjects - Section 4.1. If the research will include a clinical trial, even if exempt, include a Data and Safety Monitoring Plan as described in Section 4.1.5, and address the ClinicalTrials.gov requirements if applicable – Section 4.1.6.
- Inclusion of Women and Minorities - Section 4.2
- Targeted/Planned Enrollment - Section 4.3
- Inclusion of Children - Section 4.4

Scenario E: Clinical Trial

Criteria

Human Subjects Research	Yes
Exemption	Yes or No
Clinical Trial	Yes

Instructions and Required Information

In the application narrative, provide the required information for each of the following topics below:

- Protection of Human Subjects - Section 4.1 - 4.1.6
- Inclusion of Women and Minorities - Section 4.2
- Targeted/Planned Enrollment - Section 4.3
- Inclusion of Children - Section 4.4

If the research involves collaborating sites or subprojects, provide the information identified above for each participating site.

4. Instructions Pertaining to Non-Exempt Human Subjects Research

In your Project Narrative, include information pertaining to the protection of human subjects, inclusion of women and minorities, targeted/planned enrollment,and inclusion of children, if required. Although no specific page limitation applies to this section of the application, be succinct. Scientific Review Groups will assess each application as being acceptable or unacceptable with regard to the protection of human subjects. HHS regulations and policies governing human subjects research are described and referenced in Section 5 below. Use subheadings to address the issues listed under items 4.1-4.4 below. If your research includes a clinical trial, include a subheading "Data and Safety Monitoring Plan" and follow the instructions in 4.1.5 below.

4.1 Protection of Human Subjects

4.1.1 Risks to Human Subjects

a. ***Human Subjects Involvement, Characteristics, and Design***

- Describe the proposed involvement of human subjects in the work outlined in the Research Strategy section.
- Describe and justify the characteristics of the subject population, including their anticipated number, age range, and health status if relevant.
- Describe and justify the sampling plan, as well as the recruitment and retention strategies and the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that

'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.

- If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects protection, describe and justify the selection of an intervention's dose, frequency, and administration.
- List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data from the site(s) will be obtained, managed, and protected.

b. ***Sources of Materials***

- Describe the research material obtained from living individuals in the form of specimens, records, or data.
- Describe any data that will be collected from human subjects for the project(s) described in the application.
- Indicate who will have access to individually identifiable private information about human subjects.
- Provide information about how the specimens, records, and/or data are collected, managed, and protected as well as whether material or data that include individually identifiable private information will be collected specifically for the proposed research project.

c. ***Potential Risks***

- Describe the potential risks to subjects (physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the human subjects.
- Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research.

4.1.2 Adequacy of Protection Against Risks

a. ***Recruitment and Informed Consent***

- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Informed consent document(s) need not be submitted to the PHS agencies unless requested.

b. ***Protections Against Risk***

- Describe planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.
- Research involving vulnerable populations, as described in the HHS regulations, Subparts B-D must include additional protections. Refer to HHS regulations, and OHRP guidance:
- Additional Protections for Pregnant Women, Human Fetuses and Neonates: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb
- Additional Protections for Prisoners: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc
- OHRP Subpart C Guidance: http://www.hhs.gov/ohrp/policy/index.html#prisoners
- Additional Protections for Children: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd
- OHRP Subpart D Guidance: http://www.hhs.gov/ohrp/policy/index.html#children
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a general description of the plan for data and safety monitoring of clinical trials and adverse event reporting to the IRB, HRSA and others, as appropriate, to ensure the safety of subjects.

4.1.3 Potential Benefits of the Proposed Research to Human Subjects and Others

- Discuss the potential benefits of the research to research participants and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

4.1.4 Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

NOTE: Test articles (investigational new drugs, devices, or biologics) including test articles that will be used for purposes or administered by routes that have not been approved for general use by the Food and Drug Administration (FDA) must be named. State whether the 30-day interval between submission of applicant certification to the FDA and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the FDA, and/or the status of requests for an

Investigational New Drug (IND) or Investigational Device Exemption (IDE) covering the proposed use of the test article in the Research Plan.

4.1.5 Data and Safety Monitoring Plan

The PHS Data and Safety Monitoring Plan Policy is described and referenced in Section 5.3.

- If the proposed research includes a clinical trial, create a heading entitled "Data and Safety Monitoring Plan."
- Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring. Describe the entity that will be responsible for monitoring and the process by which Adverse Events (AEs) will be reported to the Institutional Review Board (IRB), the funding I/C, and the Food and Drug Administration (FDA) in accordance with Investigational New Drug (IND) or Investigational Device Exemption (IDE) regulations. Be succinct. Contact the FDA (http://www.fda.gov/) and also see the following Web sites for more information related to IND and IDE requirements:
  http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr312_01.html (IND)
  http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr812_01.html (IDE)
- The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

  a. PD/PI (required)
  b. Institutional Review Board (IRB) (required)
  c. Independent individual/safety officer
  d. Designated medical monitor e. Internal Committee or Board with explicit guidelines f. Data and Safety Monitoring Board (DSMB). PHS specifically requires the establishment of Data and Safety Monitoring Boards (DSMBs) for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials may also need DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.
- A detailed Data and Safety Monitoring Plan must be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to the accrual of human subjects.

4.1.6 ClinicalTrials.gov Requirements

Public Law 110-85 (also known as the FDA Amendments Act (FDAAA) of 2007) mandates registration and results reporting of certain "applicable clinical trials" in ClinicalTrials.gov. Under the statute these trials generally include: (1) Trials of Drugs

and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and (2) Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance. Review the statutory definition of applicable clinical trial to identify if registration is required to comply with the law (See PL 110-85, Section 801(a), adding new 42 U.S.C. 282(j)(1)(A)).

PHS encourages registration of ALL clinical trials whether required under the law or not. Registration is accomplished at the ClinicalTrials.gov Protocol Registration System Information Web site (http://prsinfo.clinicaltrials.gov/). A unique identifier called an NCT number, or ClinicalTrials.gov registry number, will be generated during the registration process.

The PHS implementation of FDAAA requires:

- the registration of applicable clinical trials in ClinicalTrials.gov no later than 21 days after the first subject is enrolled,
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA, and
- if an “applicable clinical trial” is funded in whole or in part by an PHS grant or cooperative agreement, grant and progress report forms shall include a certification that the responsible party has made all required submissions to ClinicalTrials.gov.

For competing (new and renewal) applications that include applicable clinical trials which require registration and, in certain cases, require results reporting under FDAAA, provide the NCT number/s, Brief Title/s (protocol title intended for the lay public), and the identity (name, organization) of the responsible party and their contact information (e-mail address is required for internal administrative use only) in the human subjects section of the Research Plan under a section heading entitled ClinicalTrials.gov. If a new applicable clinical trial is proposed, or if the grant will support an applicable clinical trial that is ongoing but not yet required to register under FDAAA (e.g. less than 21 days have passed since enrollment of the first patient), the human subjects section of the Research Plan must include a clear statement, under the heading ClinicalTrials.gov, that the project includes an applicable clinical trial which will require registration in ClinicalTrials.gov.

The entity responsible for registering the trial is the "responsible party". The statute defines the responsible party as:

1) the sponsor of the clinical trial (as defined in 21 CFR 50.3) (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.3), or
2) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee (provided that "the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements" for submitting information under the law) (http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf). See PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)(ix)).

The signature on the application of the Authorized Organization Representative assures compliance with FDAAA.

4.2 Inclusion of Women and Minorities

In the Program Narrative, section on Protection of Human Subjects, include a heading entitled "Inclusion of Women and Minorities." Although no specific page limitation applies to this section of the application, be succinct. The PHS Policy on the Inclusion of Women and Minorities in Clinical Research is described and referenced in Section 5.5. Scientific Review Groups will assess each application as being acceptable or unacceptable with regard to the inclusion of women and minorities in clinical research. In this section of the Research Plan, address, at a minimum, the following four points:

1) The targeted/planned distribution of subjects by sex/gender and racial/ethnic groups for each proposed study or protocol using the format in the Targeted/Planned Enrollment Table. (Instructions for completing this table are provided below in Section 4.3.) If using existing specimens and/or data without access to information on the distribution of women and minorities, so state and explain the impact on the goals of the research as part of the rationale that inclusion cannot be described (item 3 below). Alternatively, describe the gender and minority composition of the population base from whom the specimens and/or data will be obtained. Include the Targeted/Planned Enrollment Tables in this section.
2) A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
3) A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group (see examples below).
4) A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.

Below are examples of acceptable justifications for the exclusion of:

A. ***One gender:***

1) One gender is excluded from the study because:
   - inclusion of these individuals would be inappropriate with respect to their health;
   - the research question addressed is relevant to only one gender;
   - evidence from prior research strongly demonstrates no difference between genders; or
   - sufficient data already exist with regard to the outcome of comparable studies in the excluded gender, and duplication is not needed in this study.
2) One gender is excluded or severely limited because the purpose of the research constrains the applicant's selection of study subjects by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or overriding factors dictate selection of subjects, such as matching of transplant recipients, or availability of rare surgical specimens).
3) Gender representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete gender documentation are used), and this does not compromise the scientific objectives of the research.

B. ***Minority groups or subgroups:***

1) Some or all minority groups or subgroups are excluded from the study because:
   - inclusion of these individuals would be inappropriate with respect to their health;
   - the research question addressed is relevant to only one racial or ethnic group;
   - evidence from prior research strongly demonstrates no differences between racial or ethnic groups on the outcome variables;
   - a single minority group study is proposed to fill a research gap; or
   - sufficient data already exists with regard to the outcome of comparable studies in the excluded racial or ethnic groups and duplication is not needed in this study.
2) Some minority groups or subgroups are excluded or poorly represented because the geographical location of the study has only limited numbers of these minority groups who would be eligible for the study, and the investigator has satisfactorily addressed this issue in terms of:
   - the size of the study;
   - the relevant characteristics of the disease, disorder or condition; or
   - the feasibility of making a collaboration or consortium or other arrangements to include representation.
3) Some minority groups or subgroups are excluded or poorly represented because the purpose of the research constrains the applicant's selection of study subjects by race or ethnicity (e.g., uniquely valuable cohorts, stored specimens or existing datasets are of limited minority representation, very small numbers of subjects are involved, or overriding factors dictate selection of subjects, such as matching of transplant recipients or availability of rare surgical specimens).
4) Racial or ethnic origin of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens or data sets with

incomplete racial or ethnic documentation are used) and this does not compromise the scientific objectives of the research.

4.3 Instructions for Completing Information on the Targeted/Planned Enrollment for Reporting Race and Ethnicity Data for Subjects in Clinical Research

The PHS Policy on Reporting Race and Ethnicity Data for Subjects in Clinical Research is described and referenced in Section 5.7.

A. New Applications

All new clinical research studies should collect and report information on participants with respect to two categories of ethnicity and five categories of race.

When reporting these data in the aggregate, investigators should report: (a) the number of research participants in each ethnic category; (b) the number of research participants who selected only one category for each of the five racial categories; (c) the total number of research participants who selected multiple racial categories reported as the "number selecting more than one race," and (d) the number of research participants in each racial category who are Hispanic or Latino. Investigators may provide the detailed distributions, including all possible combinations, of multiple responses to the racial designations as additional information. However, more detailed data should be compiled in a way that they can be reported using the required categories.

Instructions for Completing Information on Targeted/Planned Enrollment

Provide the study title.

The "Total Planned Enrollment" means the number of subjects that are expected to be enrolled in the study, consistent with the definition in ClinicalTrials.gov.

The "Total Planned Enrollment" will be reported in two ways : by "Ethnic Category" and by "Racial Categories."

"Ethnic Category": Provide the numeric distribution of the Total Planned Enrollment according to ethnicity and sex/gender.

"Racial Categories": Provide the numeric distribution of the Total Planned Enrollment, this time by racial categories and sex/gender. Note that Hispanic is an ethnic, not a racial, category.

List any proposed racial/ethnic subpopulations.

Describe how the project will assure cultural competence in terms of including individuals from the study population in the planning and implementation of the research

project and in adapting the research methodology to reflect an understanding of and valuing of the culture of the study population.

Submitting Applications or Proposals Using Existing Data in Clinical Research with No Plans for Collecting New/Additional Data:

Investigators are instructed to provide plans for the total number of subjects proposed for the study and to provide the distribution by ethnic/racial categories and sex/gender. Under these circumstances, investigators are not required to re-contact subjects solely to comply with the newly revised categories.

4.4 Inclusion of Children

The PHS Policy on Inclusion of Children is referenced and described in Section 5.6. Instructions for inclusion in the Program Narrative, section on the Protection of Human Subjects are as follows:

- Create a section entitled “Inclusion of Children” and place it immediately following the Targeted/Planned Enrollment Table.
- For the purpose of implementing these guidelines, a *child* is defined as an individual under the age of 21 years.
- Provide either a description of the plans to include children, or, if children will be excluded from the proposed research, application, or proposal, present an acceptable justification for the exclusion (see below).
- If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan also must include a description of the expertise of the investigative team for working with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.
- Scientific Review Groups will assess each application as being acceptable or unacceptable with regard to the age-appropriate inclusion or exclusion of children in the proposed research project.
- When children are involved in research, the Additional Protections for Children Involved as Subjects in Research (45 CFR part 46 Subpart D) apply and must be addressed under the Protections Against Risk subheading (4.1.2.b).

Justifications for Exclusion of Children

For the purposes of this policy, all individuals under 21 are considered children; however, exclusion of any specific age group, such as individuals under 18, should be justified in this section. It is expected that children will be included in all clinical research unless one or more of the following exclusionary circumstances apply:

1) The research topic to be studied is not relevant to children.
2) Laws or regulations bar the inclusion of children in the research.
3) The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be needlessly redundant. Documentation of other studies justifying the exclusions should be provided. HRSA program staff can be contacted for guidance on this issue if the information is not readily available.
4) A separate, age-specific study in children is warranted and preferable. Examples include:
    a. The condition is relatively rare in children, as compared to adults (in that extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition); or
    b. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
    c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages or different age-related metabolic processes). While this situation may represent a justification for excluding children in some instances, consideration should be given to taking these differences into account in the study design and expanding the hypotheses tested, or the interventions planned, to allow inclusion of children rather than excluding them.
5) Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). Although children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis.
6) Study designs are aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children).
7) Other special cases can be justified by the investigator and found acceptable to the review group and the funding agency.

5. Human Subjects Research Policy

Human Subjects Research Policy includes HHS regulations for the protection of human subjects and the following PHS policies related to human subjects research.

5.1 Protection of Human Subjects

The Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects provide a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the HHS. The regulations stipulate that the awardee organization, whether domestic or foreign, bears responsibility for safeguarding the rights and welfare of human subjects in HHS-supported research activities. The regulations require that all organizations engaged in nonexempt human subjects research supported or conducted by the HHS hold a Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP), and establish appropriate policies and procedures for the protection of human subjects. These regulations, 45 CFR part 46, Protection of Human Subjects, are available from OHRP, Department of Health and Human Services, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; telephone: 1-866-447-4777 (toll-free) or (240) 453-6900; E-mail: ohrp@osophs.dhhs.gov. In general, OHRP considers organizations that receive direct support from HHS for the conduct of nonexempt human subjects research to be engaged in human subjects research (for more information on whether an institution is engaged in human subjects research, refer to: http://www.hhs.gov/ohrp/policy/engage08.html). When a research project is conducted by multiple organizations, each organization that is engaged in nonexempt human subjects research must hold an FWA and comply with the regulations at 45 CFR 46.

Nonexempt research involving human subjects may only be conducted under a HHS award if the engaged organization(s) is operating in accord with an approved FWA and provides verification that an Institutional Review Board (IRB) that is registered with OHRP has reviewed and approved the proposed activity in accordance with the HHS regulations. No award will be made unless the applicant is affiliated with an assured organization that accepts responsibility for compliance with the HHS regulations. Foreign applicant organizations must also comply with the provisions of the regulations unless a determination of equivalent protections is made in accord with 45 CFR 46.101(h).

Under HHS regulations to protect human subjects, certain research areas are exempt. However, if an applicant makes inappropriate designations of the noninvolvement of human subjects or of exempt categories of research, this may result in delays in the review of an application or an application not being reviewed. The PHS will make a final determination as to whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the Research Plan. With the exception of research projects that meet the criteria for Exemption 4, studies

that are exempt from the human subjects regulatory requirements must still address the inclusion of women, minorities and children in the study design.

Regulations of the Food and Drug Administration (21 CFR 50, 21 CFR 56) generally apply to biomedical research involving an unapproved drug, device or biologic and may apply to certain studies of approved products. Additional information on FDA regulations is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm. If work falls under FDA's regulatory requirements, the grantee must follow both HHS and FDA human subject protection regulations.

Federal requirements to protect human subjects apply to most research on human specimens (such as cells, blood, and urine), residual diagnostic specimens, and medical information. Research involving existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that are individually identifiable is considered “research involving human subjects.”

The HHS regulations require the PHS to evaluate all applications and proposals involving human subjects (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.120). This independent evaluation is conducted at HRSA through the objective review system and HRSA staff review, and, as required, will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. On the basis of this evaluation, HRSA may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

5.2 Vulnerable Populations

Investigators who conduct research involving pregnant women, human fetuses and neonates, prisoners (or subjects who become prisoners after the research has started) or children, must follow the provisions of the regulations in Subparts B, C, and D of 45 CFR part 46, respectively. The subparts describe the additional protections required for conducting research involving these populations. Relevant information may be obtained at the OHRP Web site (http://www.hhs.gov/ohrp/policy/index.html).

Exemptions 1-6 do **not** apply to research involving prisoners or subjects who become prisoners (see Subpart C). Although Exemptions 1 and 3-6 apply to research involving children (see Subpart D), Exemption 2 can only be used for research involving educational testing or observations of public behavior when the investigator(s) do not participate in the activities being observed.

5.3 Data and Safety Monitoring Plans for Clinical Trials

For each proposed clinical trial, PHS requires a data and safety monitoring plan that describes oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. Prior to the accrual of human subjects, a detailed data and safety monitoring plan must be submitted to the applicant's IRB and to the funding entity for approval. Adverse Events must be reported to the IRB, the PHS funding Institute or Center, and other appropriate offices or agencies. This policy requirement is in addition to any monitoring requirements imposed by 45 CFR part 46. PHS policy specifically requires the establishment of a Data and Safety Monitoring Board (DSMB) for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. A DSMB also may be appropriate for clinical trials if the studies are blinded (masked), employ high-risk interventions, or involve vulnerable populations.

Summary reports of adverse events must be provided to HRSA and to individual IRBs in order for them to address reports related to the site for which they have responsibility. Grantees should address questions on this subject to the HRSA Program Official.

5.4 IRB Approval

HRSA does not require certification of IRB approval of the proposed research prior to HRSA objective review of an application.

Following HRSA objective review, applicants and their institutions will be notified of the need for review and approval of the proposed research by an IRB that is registered with OHRP. See http://www.hhs.gov/ohrp/ to register an IRB. Certification of IRB approval must be sent to the Grants Management Office identified in the notice requesting documentation. Certification of IRB review and approval must include: the PHS application number, title of the project, name of the program director /principal investigator, date of IRB approval, and appropriate signatures. Grantees may also use the optional form "Protection of Human Subjects - Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule)" (OMB Form No. 0990-0263 http://www.hhs.gov/ohrp/assurances/forms/of310.rtf) to meet this requirement.

According to OHRP policy, in general, an institution is considered to be engaged in human subjects research when it receives a HRSA award to support nonexempt human subjects research. See http://www.hhs.gov/ohrp/policy/engage08.html. All institutions engaged in human subjects research must obtain a Federal Wide Assurance (FWA) from OHRP. Instructions for applying for a Federal Wide Assurance (FWA) are available from the OHRP Web site at http://www.hhs.gov/ohrp/assurances/index.html.

HHS human subject regulations at 45 CFR46.103(f) require that each application for non-exempt HHS-supported human subject research be reviewed and approved by an IRB (see also http://www.hhs.gov/ohrp/policy/conditionalapproval2010.html). Only the

date of approval of the application should be submitted to HRSA. However, the IRB must ensure that any corresponding protocol(s) are consistent with the application, and must maintain documentation of IRB approval of all corresponding protocols, including those reviewed by consortium participants. For multi-site research, the primary grantee is expected to collect the certification from each subrecipient.

Any modifications to the Research Plan in the application, required by either HRSA or by the IRB, must be submitted with follow-up certification of IRB approval to HRSA before the competing award is made. It is the responsibility of the PD/PI and the applicant organization to submit the follow-up documentation. If more than a year will have elapsed between the initial IRB review date and the anticipated award date, the awarding unit staff will require re-review by the IRB prior to award.

5.5 PHS Policy on the Inclusion of Women and Minorities in Clinical Research

PHS policy requires that women and members of minority groups and their subpopulations must be included in all PHS-supported biomedical and behavioral research projects involving clinical research unless a clear and compelling rationale and justification establishes to the satisfaction of the funding agency that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances must be designated by the Director, PHS, upon the recommendation of an agency based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. All PHS-supported biomedical and behavioral research involving human subjects is defined as clinical research. This policy applies to research subjects of all ages.

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. The Research Plan should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a rationale for selection of such subjects. Such a plan should contain a description of the proposed outreach programs for recruiting women and minorities as participants.

5.6 PHS Policy on Inclusion of Children

Research involving children must comply with the PHS Policy and Guidelines on the Inclusion of Children in Clinical Research.

PHS policy requires that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the PHS unless there are clear and compelling reasons not to include them. Therefore, proposals for clinical research must include a description of plans for including children. If children will be excluded from the

research, the application or proposal must present an acceptable justification for the exclusion.

The involvement of children as subjects in research must be in compliance with all applicable subparts of 45 CFR part 46 as well as with other pertinent federal laws and regulations.

IRBs have special review requirements to protect the well-being of children who participate in research. These requirements relate to risk, benefit, parental/guardian consent, and assent by children, and to research involving children who are wards of the state or of another institution. The local IRB approves research that satisfies the conditions set forth in the regulations.

5.7 PHS Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research

The Office of Management and Budget (OMB) defines minimum standards for maintaining, collecting and presenting data on race and ethnicity for all federal reporting agencies (including HRSA) in OMB Directive 15, http://www.whitehouse.gov/omb/fedreg_1997standards. The standards were revised in 1997 and include two ethnic categories (Hispanic or Latino and Not Hispanic or Latino) and five racial categories (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White). Reports of data on race and ethnicity shall use these categories. The categories in this classification are social-political constructs and should not be interpreted as being anthropological in nature. HRSA is required to use these definitions to allow comparisons to other federal databases, especially the census and national health databases. The following definitions apply to the minimum standards for the ethnic and racial categories.

Ethnic Categories:

- **Hispanic or Latino:** A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, “Spanish origin,” can be used in addition to “Hispanic or Latino.”
- **Not Hispanic or Latino**

Racial Categories:

- **American Indian or Alaska Native:** A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.
- **Asian:** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand,

and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

- **Black or African American:** A person having origins in any of the black racial groups of Africa. Terms such as “Haitian” or “Negro” can be used in addition to “Black or African American.” **Native Hawaiian or Other Pacific Islander:** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Ethnic/Racial Subpopulations: In addition to OMB ethnic and racial categories, HRSA uses the following definition for ethnic/racial subpopulations:

- Subpopulations: Each ethnic/racial group contains subpopulations that are delimited by geographic origins, national origins, and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/or cultural heritage. Attention to subpopulations also applies to individuals who self identify with more than one race. These ethnic/racial combinations may have biomedical, behavioral, and/or social-cultural implications related to the scientific question under study.

Guidance on Collecting Race and Ethnicity Data from Human Subjects

When an investigator is planning to collect data on ethnicity and race, the categories identified above should be used. The collection of greater detail is encouraged, for example on ethnic/racial subpopulations. However, any collection that uses more detail must be designed in a way that data can be aggregated into these minimally required categories. Use self-report or self-identification to collect this information by asking two separate questions – one on ethnicity and one on race. Collect ethnicity information first followed by the question on race and provide subjects with the option to select more than one racial category.

See PHS Policy on Inclusion of Women and Minorities.

5.8 ClinicalTrials.gov Requirements

In checking the "I agree" box on line 17 of the SF-424 (R&R) Cover component, the Authorized Organization Representative of the applicant organization certifies that if the research includes an applicable clinical trial under Public Law 110-85, the applicant organization will be in compliance with the registration and reporting requirements of Public Law 110-85, enacted 09/27/2007, if applicable (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf). The law amends the Public Health Service Act to expand the scope of clinical trials that must be registered in ClinicalTrials.gov. It also increases the number of registration fields that must be submitted, requires certain results information to be included, and sets penalties for noncompliance.

The trials that must be registered are called "applicable clinical trials." Under the statute these trials generally include: (1) Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and (2) Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance. HRSA encourages registration of ALL trials whether required under the law or not.

When registering clinical trials in the ClinicalTrials.gov Protocol Registration System, if applicable, enter the HRSA Grant Number associated with the trial in the "Secondary ID" field; include activity code, institute code and 5-digit serial number.

The entity responsible for registering the trial is the "responsible party."

Exemptions. The six categories of research exempt from the HHS human subject regulations are:

> ***Exemption 1:*** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
>
> ***Exemption 2:*** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
> (i) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Exemption 2 for research involving survey or interview procedures or observation of public behavior, does not apply to research with children (see 45 CFR part 46, Subpart D), except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Exemption 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exemption 4: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

The humans subjects regulations decision charts (http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html) of the Office for Human Research Protection (OHRP) will determine whether the research falls under the human subjects regulations and if so, whether it meets the criteria for Exemption 4.

Research that meets the criteria for Exemption 4 is not considered "clinical research" as defined by PHS. Therefore the PHS policies for inclusion of women, minorities and children in clinical research, do not apply to research projects covered by Exemption 4.

Exemption 5: Research and demonstration projects that are conducted by or subject to the approval of Department or Agency heads and that are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs (ii) procedures for obtaining benefits or services under those programs (iii) possible changes in or alternatives to those programs or procedures or (iv) possible changes in methods or levels of payment for benefits or services under those programs. Note: It is uncommon for investigators applying for a PHS grant to qualify for this exemption. Please seek guidance from HRSA staff if you think your project is eligible for Exemption 5.

Exemption 6: Taste and food quality evaluation and consumer acceptance studies (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or

below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.