U.S. Department of Health and Human Services

HRSA
Health Resources & Services Administration

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 Workspace Application Package

*Use with HRSA notices of funding opportunities (NOFOs) that specify use of the **SF-424 R&R** Workspace Application Package*

Updated April 19, 2024

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1. INTRODUCTION

1.1. About HRSA

Our programs provide equitable health care to people who are geographically isolated and economically or medically vulnerable. This includes programs that deliver health services to people with HIV, pregnant people, mothers and their families, those with low incomes, residents of rural areas, American Indians and Alaska Natives, and those otherwise unable to access high-quality health care.

Our programs also support health infrastructure, including through training of health professionals and distributing them to areas where they are needed most, providing financial support to health care providers, and advancing telehealth.

In addition, we oversee programs for providing discounts on prescription drugs to safety net providers, facilitating organ, bone marrow, and cord blood transplantation, compensating individuals injured by vaccination, and maintaining data on health care malpractice payments.

In Fiscal Year 2021, we provided nearly $54 billion in funding to support our mission. For more information, visit the HRSA Agency Overview page and explore data and maps on our health care programs.

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 competing continuation, competing supplement, limited competition, and new applications electronically to HRSA through Grants.gov. This *R&R Application Guide* is specific to HRSA notices of funding opportunities (NOFOs) using the Application for Federal Assistance SF-424 Research and Related (R&R) application package[1] **for research or training awards. HRSA requires you to submit electronically**. This *Guide* presents 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 NOFOs.

Note: To request a subsequent budget period, recipients 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, visit HRSA's Non-Competing Continuation Process page.

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

1.3. Document Version Control

HRSA's Division of Grants Policy in the Office of Federal Assistance and Acquisition Management periodically updates and maintains this document.

1.4. Summary of Significant Changes

April 19, 2024

- Added citations regarding the Further Consolidated Appropriations Act, 2024 (P.L. 118-47).
- Added Registering in ID.me for Payment Management System (PMS) Access guidance for successful applicants who receive an award.

April 1, 2024

- Updated Project Abstract guidance: removed bulleted list. We no longer require *specific contact details* in the Project Abstract Summary form.

January 12, 2024

- Updated **Accessibility Provisions and Non-Discrimination Requirements** in Section 2.1. Administrative and National Policy Requirements.
- Updated Executive Level II salary rate limitation amount from $212,100 to **$221,900** to align with OPM's Salary Table No. 2024-EX. Also updated related salary breakdowns and examples.
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2. POLICIES, ASSURANCES, DEFINITIONS, AND OTHER INFORMATION

2.1. Administrative and National Policy Requirements

Successful applicants are required to comply with 45 CFR part 75 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (UAR).

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

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.

Internal controls must be in place to ensure that costs charged to HRSA awards are allowable, allocable to the HRSA award, reasonable, necessary, and documented. For example, controls must be in place to ensure that only actual time worked on HRSA projects are charged to HRSA awards, and that the time worked has management approval from the HRSA award recipient. There also must be internal controls in place to ensure that costs charged to HRSA awards through subawards are monitored and evaluated by the HRSA award recipient and that only allowable, allocable, reasonable, necessary and documented costs are charged to HRSA awards.

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.]

Accessibility Provisions and Non-Discrimination Requirements

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to this when you register in SAM.gov. You must also submit an Assurance of Compliance (HHS-690). To learn more, see the Laws and Regulations Enforced by the HHS Office for Civil Rights.

Contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws or call 1-800-368-1019 or TDD 1-800-537-7697.

The HRSA Office of Civil Rights, Diversity, and Inclusion (OCRDI) offers technical assistance, individual consultations, trainings, and plain language materials to supplement OCR guidance. Visit OCRDI's website to learn more about how federal civil rights laws and accessibility requirements apply to your programs, or contact OCRDI directly at HRSACivilRights@hrsa.gov.

Acknowledgment of Federal Funding

If the NOFO notes that the program is subject to the General Provisions of P.L. 118-47 (or P.L. 117-328), the following statutory/legislative mandate applies:

Division D, Title V, 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.

In addition, HRSA requires recipients to use the following acknowledgment and disclaimer:

> "This [project/publication/program/website] [is/was] supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $XX with xx percentage financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, 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. For more details, see HRSA's Communicating and Acknowledging Federal Funding webpage.

Conflict of Interest

HRSA has established a Federal Financial Assistance Conflict of Interest Policy (COI Policy) pursuant to 45 CFR § 75.112, which requires that awarding agencies establish conflict of interest policies for federal awards that: 1) Address conditions under which outside activities, relationships, or financial interests are proper or improper; 2) Provide for advance notification of outside activities, relationships, or financial interests, and a process of review as appropriate; and 3) Outline how financial conflicts of interest may be addressed. This policy addresses such conditions; identifies when and how a non-federal entity (NFE) must provide written notification of such outside activities, relationships, or financial interests to HRSA or, in the case of grant subrecipients, to the pass-through entity, and describes a process of review of such disclosures; and discusses the means by which financial conflicts of interest may be addressed.

This COI Policy, except as noted below, applies to all NFEs receiving HRSA financial assistance, either directly (from HRSA) or indirectly (i.e., through a subaward from a pass-through entity). Note: For the purposes of this COI Policy, institutions of higher education that are instrumentalities of a state under applicable state laws are subject to the requirements applicable to such entities.

Financial Conflict of Interest

HHS requires recipients 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. 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.

Healthy People 2030

Led by HHS, Healthy People 2030 is the nation's 10-year plan for addressing our most critical public health priorities and challenges. Since 1980, HHS's Office of Disease Prevention and Health Promotion has set measurable objectives and targets to improve the health and well-being of the nation.

This decade, Healthy People 2030 features 355 core – or measurable – objectives with 10-year targets, new objectives related to opioid use disorder and youth e-cigarette use, and resources for adapting Healthy People 2030 to emerging public health threats like COVID-19. For the first time, Healthy People 2030 also sets 10-year targets for objectives related to social determinants of health. More information about Healthy People 2030 may be found online at https://health.gov/healthypeople.

Human Subjects Protection

Federal regulations (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, recipients 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.

NOTE: See the Appendix of this *R&R Application Guide* for supplemental instructions for preparing the human subjects section of the research plan.

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. 3354).

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: https://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
Email: grantdisclosures@oig.hhs.gov

Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment

(a) As described in 2 CFR § 200.216, recipients and subrecipients are prohibited to obligate or spend grant funds (to include direct and indirect expenditures as well as cost share and program) to:

(1) Procure or obtain,

(2) Extend or renew a contract to procure or obtain; or

(3) Enter into contract (or extend or renew contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Pub. L. 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

i. For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

ii. Telecommunications or video surveillance services provided by such entities or using such equipment.

iii. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

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.

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. 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.

Trafficking in Persons

Awards issued under HRSA NOFOs 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 Trafficking Victims Protection.

NOTE: The signature of the Authorized Organization Representative (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.

2.2. Compliance Requirements at a Glance

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

Recipient Type	Administrative Requirements	Cost Principles	Audit Requirements
State, Local & Tribal Governments	45 CFR part 75	45 CFR part 75; subpart E	45 CFR part 75; subpart F
Colleges & Universities	45 CFR part 75	45 CFR part 75; subpart E	45 CFR part 75; subpart F
Non-Profits	45 CFR part 75	45 CFR part 75; subpart E	45 CFR part 75; subpart F

Recipient Type	Administrative Requirements	Cost Principles	Audit Requirements
Hospitals	45 CFR part 75	45 CFR part 75, Appendix IX	45 CFR part 75; subpart F
For-Profits	45 CFR part 75	48 CFR subpart 31.2 (FAR 31.2)	45 CFR part 75; subpart F
Foreign	45 CFR part 75	As stated above for each recipient 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.

2.3. Assurances and Certifications

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

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the forms themselves are no longer required to be part of HRSA's Application Package and the updated common certification and representation requirements will be stored and maintained within the System for Award Management (SAM). Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications and representations annually through SAM.

2.4. References

About HRSA

How to Apply for a HRSA Grant

System for Award Management (SAM) | SAM.gov Knowledge Base

Grants.gov Online User Guide

Grants.gov Workspace Overview

Tips for Preparing Grant Proposals

2.5. Definitions

Please refer to 45 CFR § 75.2 Definitions.

2.6. Acronyms

AL	Assistance Listings (formerly the Catalog of Federal Domestic Assistance (CFDA))
AO	Authorizing Official
AOR	Authorized Organization Representative
BPHC	Bureau of Primary Health Care
BHW	Bureau of Health Workforce
CAS	**Cost Allocation Services**
CCR	Central Contractor Registration (now defunct)
CFR	Code of Federal Regulations
CGMO	Chief Grants Management Officer
DSO	Digital Services Operation
DUNS	Data Universal Numbering System
EBiz POC	E-Business Point of Contact
EHBs	Electronic Handbooks
EIN	Employer Identification Number
EO	Executive Order
FAQ	Frequently Asked Questions
FAR	Federal Acquisition Regulation
FFATA	Federal Funding Accountability and Transparency Act
FORHP	Federal Office of Rural Health Policy
FY	Fiscal Year
F&A	Facilities and Administration
GMO	Grants Management Officer

GMS	Grants Management Specialist
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
NOFO	Notice of Funding Opportunity
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
PO	Project Officer / Program Official
POC	Point of Contact
R&R	Research and Related
SAM	System for Award Management
SF	Standard Form
TA	Technical Assistance
TIN	Tax Identification Number
UEI	Unique Entity Identifier

3. REGISTERING AND APPLYING THROUGH GRANTS.GOV USING WORKSPACE

Grants.gov Application Submission and Receipt Procedures

This section provides the application submission and receipt instructions for HRSA program applications. Read the following instructions carefully and completely.

3.1. Electronic Delivery

HRSA is participating in the Grants.gov initiative to provide the grant community with a single site to find and apply for funding opportunities. HRSA requires you to submit your applications online.

- **NOTE:** HRSA highly recommends that you complete the Grants.gov registration process at least 4 WEEKS before your organization's first Grants.gov submission.

3.2. How to Register to Apply through Grants.gov

a. *Instructions:* Read the instructions below about registering to apply for HRSA funds. You should read the registration instructions carefully and prepare the information requested before beginning the registration process. Reviewing and assembling the required information before beginning the registration process will alleviate last-minute searches for required information.
The registration process can take up to 4 weeks to complete. Therefore, registration should be done in sufficient time to ensure it does not impact your ability to meet required application submission deadlines.

If individual applicants are eligible to apply for this funding opportunity, refer to: Grants.gov: Individual Registration.

Organization applicants can find complete instructions here: Grants.gov: Organization Registration.

1) *Register with SAM*: The Unique Entity Identifier (UEI) assigned by the System for Award Management (SAM), has replaced the Data Universal Numbering System (DUNS) number. Register in SAM and you will be assigned a UEI . It takes 1 day (after you enter the EBiz POC name and EBiz POC email in SAM) to receive a UEI, which will allow you to register with Grants.gov and apply for federal funding.

   All organizations must register with SAM in order to apply online. Failure to register with SAM will prevent your organization from applying through Grants.gov.

   Effective March 3, 2023, individuals assigned a SAM.gov Entity Administrator role must be an employee, officer, or board member, and cannot be a non-employee. This change is to ensure entities are in control of who has permission to control roles within their entity.

   Here's what this means:

   - Entity Administrators assigning roles to non-employees will only be able to assign a Data Entry role or lower.
   - Any entities assigning Entity Administrator roles using an Entity Administrator Role Request Letter (formerly called "notarized letter") will no longer be able to assign the Entity Administrator role to a non-employee.

- Entity Administrator roles assigned to non-employees will be converted to Data Entry roles. With a Data Entry role, non-employees can still create and manage entity registration data entry but cannot manage roles.

If you are an entity using a non-employee or if you are a non-employee working with an entity to manage registrations, please read (and share) more about this change on the BUY.GSA.gov blog to know what to expect.

Make sure you "opt-in" for public display of your record within SAM so HRSA can easily access and review your information. If you see the question "Is my information available for viewing by the public?" please answer "Yes."

For more detailed instructions for registering with SAM, refer to: Grants.gov: Applicant Registration.

2) *Create a Grants.gov Account:* The next step in the registration process is to create an account with Grants.gov. You must know your organization's UEI number to complete this process. Enter the UEI (SAM) in the data entry field labeled "UEI" on the Grants.gov SF-424 R&R form. Completing this process automatically triggers an email request for applicant roles to the organization's E-Business Point of Contact (EBiz POC) for review. The EBiz POC is a representative from your organization who is the contact listed for SAM. To apply for awards on behalf of your organization, you will need the Authorized Organizational Representative (AOR) role.
For more detailed instructions about creating a profile on Grants.gov, refer to: Grants.gov: Add Profile.

3) *Authorize Grants.gov Roles:* After creating an account on Grants.gov, the EBiz POC receives an email notifying them of your registration and request for roles. The EBiz POC will then log in to Grants.gov and authorize the appropriate roles, which may include the AOR role, thereby giving you permission to complete and submit applications on behalf of the organization. You will be able to submit your application online any time after you have been approved as an AOR.

   For more detailed instructions about creating a profile on Grants.gov, refer to: Grants.gov: Authenticate AOR

4) *Track Role Status:* To track your role request, refer to: Grants.gov: Track My Application

b. *Electronic Signature:* When submitting applications through Grants.gov, insert the name of your organization's AOR who submits the application into the signature line of the application, serving as the electronic signature. The EBiz

POC must authorize individuals who are able to make legally binding commitments on behalf of the organization as an AOR. Applicants often miss this step and it is crucial for valid and timely submissions.

3.2.1. Find Funding Opportunity

There are three ways to search for HRSA funding opportunities on Grants.gov.

1. Enter keyword or phrase in the Search box at the top of the home page at Grants.gov.
2. Click on one of the following tabs in the middle of the home page to: Browse Newest, Browse Categories, Browse Agencies, or Browse Eligibilities.
3. Click the SEARCH GRANTS tab, enter the funding opportunity number and/or assistance listings number, and then select the funding opportunity for which you wish to apply. Refer to the NOFO for eligibility criteria. Otherwise, use the various filters to help narrow your search.

Search for the funding opportunity under the APPLICANTS tab under *How to Apply for Grants*. Enter the NOFO number provided in the field, Funding Opportunity Number. (Example: HRSA-22-000.)

3.2.2. Subscribing to a NOFO

HRSA strongly recommends subscribing to NOFOs you are interested in by using the Subscribe button located next to the Apply button on the Grant Opportunity page. By subscribing and providing your email address before reviewing or preparing the workspace application package, you will receive notifications including modifications, related documents and/or republications of the NOFO on Grants.gov before its closing date.

3.3. How to Submit an Application to HRSA via Grants.gov

Grants.gov applicants can apply online using Workspace. Workspace is a shared, online environment where members of a grant team may simultaneously access and edit different webforms within an application. For each NOFO, you can create individual instances of a workspace.

Below is an overview of applying on Grants.gov. For access to complete instructions on how to apply for opportunities, refer to:
Grants.gov: Apply for Grants

1) *Create a Workspace*: Creating a workspace allows you to complete your application online and route it through your organization for review before submitting.

2) *Complete a Workspace*: Add participants to the workspace, complete all the required forms, and check for errors before submission.

a. *Adobe Reader*: If you decide not to apply by filling out webforms, you can download individual PDF forms in Workspace so that they will appear similar to other Standard or HRSA forms. You can download and save the individual PDF forms to your local device storage, network drive(s), or external drives, and then access through Adobe Reader.

   NOTE: Visit the Adobe Software Compatibility page on Grants.gov to download the appropriate version of the software at: Grants.gov: Adobe Software Compatibility

b. *Mandatory Fields in Forms:* In the forms, you will note fields marked with an asterisk and a different background color. You must complete these mandatory fields to successfully submit your application.
c. *Complete SF-424 Fields First:* The forms are designed to fill in common required fields across other forms, such as the applicant name, address, and UEI number. To trigger this feature, an applicant must complete the SF-424 information first. Once it is completed, the information will transfer to the other forms.

3) *Submit a Workspace*: You may submit an application through workspace by clicking the Sign and Submit button on the Manage Workspace page, under the Forms tab. Note: Your application will not be submitted until you complete this step. Grants.gov recommends submitting your application package at least 24–48 hours (1–2 calendar days) before the close date to provide you with time to correct any potential technical issues that may disrupt the application submission. However, HRSA suggests submitting applications to Grants.gov **at least 3 calendar days before** the deadline to allow for any unforeseen circumstances.

4) *Track a Workspace*: After successfully submitting a workspace package, a Grants.gov Tracking Number (GRANTXXXXXXXX) is automatically assigned to the package. The number will be listed on the Confirmation page that is generated after submission.

For additional training resources, including video tutorials, refer to Grants.gov: Applicant Training

Applicant Support: Grants.gov provides applicants 24/7 support via the toll-free number 1-800-518-4726 (International callers dial 1-606-545-5035) and email at support@grants.gov. For questions related to the specific funding opportunity, contact the number listed in the application package of the award you are applying for.

If you are experiencing difficulties with your submission, it is best to call the Grants.gov Support Center and get a ticket number. The Support Center ticket number will assist HRSA with tracking and understanding the issue.

3.4. Timely Receipt Requirements and Proof of Timely Submission

Online Submission. All applications must be received by 11:59 p.m. ET on the date listed in Section IV.4. Submission Dates and Times in the NOFO, unless otherwise noted. Grants.gov automatically records proof of timely submission. An electronic date/time stamp is generated within the system and sent to the AOR when Grants.gov successfully receives the application. The applicant AOR will receive an acknowledgment of receipt and a tracking number (GRANTXXXXXXXX) from Grants.gov with the successful transmission of their application serving as proof of their timely submission.

When HRSA successfully retrieves the application from Grants.gov and acknowledges the download of submissions, Grants.gov will provide an electronic acknowledgment of receipt of the application to the email address of the applicant with the AOR role. Again, proof of timely submission shall be the official date and time that Grants.gov receives your application. Applications received by Grants.gov after the established due date for the program will be considered late and HRSA will not consider the application for funding. HRSA strongly suggests that you apply **at least 3 calendar days before** the deadline to allow for any unforeseen circumstances. HRSA is under no obligation to accept applications that are late due to problems with computer systems at your organization or system-to-system grant submission service, failure to submit by the deadline, or failure to follow instructions in the Application Guide or instructions in the NOFO.

If you are using slow internet, such as dial-up connections, be aware that transmission can take some time before Grants.gov receives your application. Again, Grants.gov will provide either an error or a successfully received transmission in the form of an email sent to the applicant with the AOR role. The Grants.gov Support Center reports that some applicants end the transmission because they think that nothing is occurring during the transmission process. Please be patient and give the system time to process the application.

3.5. Late Applications

Applications which do not meet the criteria as outlined in Section IV.4. Submission Dates and Times of the NOFO will be considered late applications and will not be reviewed.

3.6. Requesting a Waiver from the Submission Requirement

HRSA **requires** you to apply electronically 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 your application electronically by the deadline posted on the NOFO. If you wish to request a waiver from the

submission requirement, you must request an exemption in writing from ApplicationWaivers@hrsa.gov **no later than 5 calendar days after the opportunity's closing date.** Requests received after 5 calendar may not be considered. The request should provide details as to why you are technologically unable to submit electronically through the Grants.gov portal. If requesting a waiver from the submission requirements, include the following in the email request:

- HRSA funding opportunity number
- Organization's name
- Address
- Telephone number
- UEI number
- Name, address, and telephone number of the PD
- 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, include those as well
- Any other details regarding the justification

HRSA's Division of Grants Management (DGMO) in the Office of Federal Assistance Management is the only office authorized to grant waivers.

HRSA is very strict on adhering to application deadlines and submission requirements. Deadline extensions will not be granted for Grants.gov verification errors, last-minute registration, or submission errors on your part. DGMO 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 (e.g.,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. DGMO will determine the affected geographical area(s) or other applicant group parameters.

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.

4. GENERAL INSTRUCTIONS FOR APPLICATION SUBMISSION

HRSA ***requires*** you to apply electronically. HRSA encourages you to apply through Grants.gov using the Standard Form 424 Research and Related (SF-424 R&R) application package associated with the funding opportunity and follow the directions provided at Grants.gov. If you use an alternative electronic submission, see Grants.gov: APPLICANT SYSTEM-TO-SYSTEM. Applications must be submitted in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

The following instructions are applicable to all submissions unless otherwise noted in the relevant NOFO. Failure to follow the instructions may make your application non-responsive. HRSA will not consider non-responsive applications and will notify applicants. It is mandatory to follow the instructions provided to ensure HRSA can efficiently and consistently print your application for review, if needed.

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.

Important note for applicants:

- Changes to improve grant award data accuracy have led HHS to require that applicant street addresses (SF-424 R&R cover page and Project/Performance Site Location Form) contain a valid 9-digit zip code. Use the following USPS.com link to find your 9-digit zip code: USPS: Look Up a Zip Code.

Unique Entity Identifier (UEI) Number

Your organization (and subrecipients of HRSA award funds) is required to have a UEI number in order to apply for a grant or cooperative agreement from the Federal Government. Include the Organizational UEI number in form SF-424 R&R (item 5 on the application face page). Applications ***will not*** be reviewed without a UEI number. Note: A missing or incorrect UEI 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 UEI number. You should take care in entering the correct UEI 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 SAM.gov.

Assistance Listings Number

The AL number, as listed on the cover of the NOFO, is prepopulated in box 10 of the form.

ii. Intergovernmental Review (Executive Order (EO) 12372)

If a NOFO is subject to EO 12372, "Intergovernmental Review of Federal Programs," it will be noted in Section IV.5. Intergovernmental Review of the funding opportunity. Refer to section16 on the SF-424 R&R.

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

> Program X is subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

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 Single Points of Contact may be obtained from the following website: Intergovernmental Review (SPOC List as of April 20, 2020).

All applicants other than federally recognized Native American tribes or tribal organizations should contact their Single Point of Contact 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 *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. Follow the instructions included in the program-specific NOFO and the instructions below when completing the project budget forms.

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[2] requirement, as applicable.

[2] If not a requirement per statute or regulation, voluntary matching or cost sharing is not considered during merit review.

Classification of Costs:

There is no universal rule for classifying certain costs as either direct or indirect facilities and administration (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:

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 5 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 NOFO notes that the program is subject to the General Provisions of P.L. 118-47 (or P.L. 117-328), the following Salary Rate Limitation applies:

Salary Rate Limitation:

The Further Consolidated Appropriations Act, 2024 (P.L. 118-47), Division D, Title II, § 202, *which supersedes the Consolidated Appropriations Act, 2023 (P.L. 117-328), Division H, Section 202,* provides 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, which is **$221,900 (*effective January 2024*)**. 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 rate limitation also applies to subrecipients under a HRSA grant or cooperative agreement. Note that these or other salary rate limitations will apply in the following fiscal years , as required by law.

See the breakdown and examples of the limitation below:

Individual's *actual* base full-time salary:	$255,000
50 percent of time will be devoted to project	
Direct salary	$127,500

Fringe (25 percent of salary)	$ 31,875
Total	$159,375

Amount that may be claimed on the application budget due to the statutory salary rate limitation:

Individual's base full-time salary *adjusted* to Executive Level II: **$221,900**
50 percent of time will be devoted to the project

Direct salary	**$110,950**
Fringe (25 percent of salary)	**$ 27,737** (rounded down)
Total amount	**$138,687** (rounded down)

Personnel Justification Table
(varied FTE percentages)

Name	Position Title	% of FTE	Base Salary	Adjusted Annual Salary*	Federal Amount Requested
J. Smith	CEO	50	$255,000	$221,900	$110,950
M. Green	Dentist	100	$225,000	$221,900	$221,900
C. Moore	Physician	50	$200,000	No adjustment needed	$100,000
R. Doe	Nurse Practitioner	100	$120,000	No adjustment needed	$120,000
H. Black	Outreach Director	50	$70,000	No adjustment needed	$35,000
D. Jones	Data/AP Specialist	25	$50,000	No adjustment needed	$12,500
	TOTAL		**$920,000**		**$600,350**

*used only when salary is over limitation of $221,900

Finally, remember that in order to be considered as allowable costs on your HRSA award, you need to ensure that personnel costs are supported by official records that accurately reflect the work performed and that internal controls provide reasonable assurance that the personnel costs are accurate, allowable, and allocable to the HRSA award.

Funding Restrictions (in general)

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

Unallowable Costs
The governing cost principles address selected items of cost. The NOFO specifies unallowable costs that apply to each funding opportunity. The following list of unallowable costs is not intended to be all-inclusive. Consult the cost principles for the complete explanation of the allowability or unallowability of costs they address.

For the full list of cost principles refer to Section 2.2 "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 statute, regulations, or the specific terms and conditions of the award, which will take precedence over the general information provided here and in the regulations that are referenced.

Also note that a cost is not allowable if it is not reasonable, necessary, allocable to the award, or adequately documented (45 CFR § 75.403).

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 law, 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	Costs of alcoholic beverages are unallowable.
Bad Debts	Unallowable.
Entertainment Costs	Conditionally 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 award, 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

Item	Description
	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 "Restrictions on Lobbying" below and at 45 CFR § 75.450 for additional descriptions and examples of prohibited activities.
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 award, 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.
Pre-award Costs	Costs incurred before 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 HRSA or authorized under expanded authority. Where authorized by HRSA as an expanded authority, a recipient may, at its own risk and without HRSA prior approval, incur obligations and expenditures to cover costs up to (and including) 90 calendar days before the

Item	Description
	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 HRSA prior approval before incurring pre-award costs. HRSA prior approval is required for any costs to be incurred more than 90 calendar days before the beginning date of the initial budget period of a new or competing continuation award.
Promotional Items (SWAG)	Promotional items and memorabilia (e.g., pencils, cups, t-shirts, cookbooks, bags), gifts, and souvenirs designed to promote the recipient's organization are unallowable as advertising/public relations costs.

Finally, even if a cost is not included on the above list, if there is not adequate documentation of particular costs, such as vouchers, invoices, timekeeping records, etc. with enough detail to determine if the cost is allowable, then the organization's annual audit might reflect that the costs cannot be charged to the HRSA award and a refund will be necessary if the costs remain undocumented.

Funding Restrictions: If the NOFO notes that the program is subject to the General Provisions of P.L. 118-47 (or P.L. 117-328), the following statutory/legislative mandates are in effect and organizations should ensure that they have policies and procedures in place, and effective financial management practices, to avoid expending any HRSA funds on prohibited activities. Your organization must comply with all legal requirements and restrictions applicable to the receipt of federal funding including statutory restrictions on use of funds for lobbying, executive salaries, gun control, abortion, etc. Like all other applicable award requirements, the effectiveness of these policies, procedures and controls is subject to audit.

Division B, Title VII

1. Confidentiality Agreements (Section 742)

Division D, Title II

2. Salary Rate Limitation (Section 202)
3. Gun Control (Section 210)

Division D, Title V

4. Anti-Lobbying (Section 503)
5. Acknowledgment of Federal Funding (Section 505)
6. Restriction on Abortions (Section 506)
7. Exceptions to Restriction on Abortions (Section 507)
8. Ban on Funding Human Embryo Research (Section 508)
9. Limitation on Use of Funds for Promotion of Legalization of Controlled Substances (Section 509)
10. Restriction of Pornography on Computer Networks (Section 520)
11. Restriction on Purchase of Sterile Needles (Section 526)

Details:

Division B, Title VII

1. Confidentiality Agreements (Section 742)

   (a) None of the funds appropriated or otherwise made available by this or any other Act may be available for a contract, grant, or cooperative agreement with an entity that requires employees or contractors of such entity seeking to report fraud, waste, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or contractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a federal department or agency authorized to receive such information.

   (b) The limitation in subsection (a) shall not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a federal department or agency governing the nondisclosure of classified information.

Division D, Title II

2. Salary Rate 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."

Effective January 2024, the Executive Level II salary increased from $212,100 to **$221,900**

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 rate limitation also applies to subawards/subcontracts under an HRSA grant or cooperative agreement.

3. 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."

Division D, Title V

4. 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."

5. 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."

6. 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."

7. 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."

8. 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."

9. 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."

10. Restriction of Pornography on Computer Networks (Section 520)

"(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."

11. Restriction on Purchase of Sterile Needles (Section 526)

"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."

v. Budget Justification Narrative

Upload the Budget Justification narrative for the entire period of performance (**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 1 or clearly indicate that there are no substantive budget changes during the period of performance. Do NOT use the budget narrative to expand the project narrative.

Budget for Multi-Year Award (periods of performance vary, maximum of 5 years)

NOFOs invite applications for periods of performance of 1 to up to 5 years. Generally, awards, on a competitive basis, will be for a 1-year budget period; although the period of performance may be up to 5 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 1-year budget period but within the multi-year period of performance is subject to availability of funds, satisfactory progress of the recipient, 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 NOFO, include the following in the Budget Justification narrative:

Personnel Costs (as listed in Sections A & B on the R&R Budget Form): Explain personnel costs 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 NOFO notes that the program is subject to the General Provisions of P.L. 118-47 (or P.L. 117-328), the following applies: Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II of $221,900. An individual's base salary, per se, is NOT constrained by the statutory 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. Provide an individual's actual base salary if it exceeds the cap. See the Personnel Justification Table in the Budget section.

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 NOFO notes that the program is subject to the General Provisions of P.L. 118-47 (or P.L. 117-328), the following applies: If an individual's base salary exceeds the statutory salary rate limitation (i.e., $221,900), 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 1 or more years). For example, large items of medical equipment.

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, outline the mileage rate, number of miles, reason for travel and staff member/consumers completing the travel. 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). Items must be listed separately.

Per 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 should not provide line item details on proposed contracts, rather you should provide the basis for your cost estimate for the contract. 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. Recipients must notify potential subrecipients that entities receiving subawards must be registered in SAM and provide the recipient with their UEI number (see 2 CFR part 25).

For subawards to entities that will help carry out the work of the award, you should decribe how you will monitor their work to ensure the funds are being properly used.

Per the Suspension and Debarment rules in the Uniform Administrative Requirements, as implemented by HRSA under 45 CFR § 75.213, 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: If allowable, 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 and provide an explanation of each cost in this category (e.g., EHR provider licenses, audit, legal counsel). 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 your project's budget, including sign interpreters, plain language and health literacy print materials in alternate formats (including Braille, large print, etc.); and linguistic competence modifications (e.g., translation or interpretation services.

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" (F&A) 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 Program Support Center (PSC). Visit PSC's Indirect Cost Negotiations website 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, attach a copy of the indirect cost rate agreement. If the indirect cost rate agreement is required per the NOFO, 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 percent 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 NOFO*. When applicable, biographical sketches should include training, language fluency and experience working with the cultural and linguistically diverse populations that are served by your programs. They should follow the format described in the NOFO and be uploaded in the SF-424 R&R Senior/Key Person Profile form. Finally, you should describe your method for ensuring that only actual work performed will be charged to the award and how that method meets federal cost principle requirements under § 75.430 Compensation—personal services.

vii. Assurances

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. See the Appendix of this *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) before 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 before 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, HHSmay 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/subrecipient.
F. A recipient may rely upon a certification of a prospective recipient in a lower tier covered transaction that neither it nor its principals[3], 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.
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.

[3] **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.

ix. Project Abstract

Use the Standard OMB-approved Project Abstract Summary form that is included in the workspace application package. Do not upload the abstract as an attachment or it may count toward any applicable page limit.

Provide a summary of the application in the Project Abstract field / box using 4,000 characters or less.

Because the abstract is often distributed to provide information to the public and Congress, 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. If the application is funded, your project abstract information (as submitted) will be made available to public websites and/or databases including USAspending.gov. See the NOFO for additional information that may be required in the project abstract.

x. Project Narrative

This section provides a comprehensive description of all aspects of the proposed project. It should be succinct, self-explanatory, consistent with forms and attachments, and well organized so that reviewers can understand the proposed project. See the NOFO for specific narrative instructions.

xi. Attachments

Provide the attachments as specified in the NOFO to complete the content of the application. You must upload attachments into the application. Any *hyperlinked* attachments will *not* be reviewed/opened by HRSA. Unless otherwise noted, attachments count toward the application page limit specified in the NOFO. **You must clearly label each attachment.**

4.2. Narrative and Attachment Formatting Guidelines

4.2.1. Font

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-point or size font. It is vital that the charts/graphs are legible when scanned or reproduced.

4.2.2. Paper Size and Margins

For duplication and scanning purposes, ensure that the application can be printed on 8½" x 11" white paper. Margins must be at least one inch at the top, bottom, left and right of the paper. Left-align text.

4.2.3. Names
Include the name of the applicant and 10-digit award 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 NOFO, do not submit organizational brochures or other promotional materials, slides, films, clips, etc.

The HRSA EHBs supports the attachment types listed below. 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 HRSA prints the application, documents will print as you have formatted them. 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

- 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 <u>rejected</u> 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 a standard order of forms (see the table on the next two pages). The NOFO 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."
- **In NOFOs with page limits:** 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	Instructions	HRSA/Program Guidelines
SF-424 R&R Cover Page	Form	Pages 1 & 2.	Required. 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	Provide information on all principals (as defined on page 36) and key personnel[3]. Supports 20 structured profiles (PD + 19 additional)	Required. Not counted in the page limit. Note: HRSA requires the "Middle Name" for each principal and key personnel submitted on the SF-424 R&R Senior/Key Person Profile form. If the principal, key personnel has no middle name, insert "N/A" on the form.
Senior Key Personnel[4] 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 requirements in the NOFO.

[4] **Key Personnel**: The Principal Investigator/Project Director (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 award.

Application Section	Form Type	Instructions	HRSA/Program Guidelines
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.	If this attachment is included, it will be 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.	If this attachment is included, it will be counted in the page limit. See Biographical Sketch requirements in the NOFO.
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.
Project/Performance Site Location(s)[5]	Form	Supports primary and 299 additional sites in structured form.	Required. Not counted in the page limit.
Additional Performance Site Location(s)[2]	Attachment	Can be uploaded in SF-424 R&R Performance Site Location(s) form. Single document with all additional site location(s).	If this attachment is included, it will be counted in the page limit.
Other Project Information	Form	Allows additional information and attachments.	Required. Not counted in the page limit.
Project Abstract Summary Form	Form	Ensure the Project Abstract field succinctly describes the project in plain language that the public can understand and use without the full proposal. Use 4,000 characters or less.	Required. Not counted in the page limit. Refer to Section 4.1ix of this *Guide* and the NOFO for detailed instructions.
Mandatory Project Narrative	Attachment	Must be uploaded in SF-424 R&R Other Project Information form, Box 8.	Required attachment. Counted in the page limit. Refer to the NOFO for detailed instructions. If necessary provide table of contents specific to this

[5] Changes to improve grant award data accuracy have led HHS to require that applicant street addresses (SF-424 R&R cover page and Project/Performance Site Location Form) contain a valid 9-digit zip code. Use the following USPS.com link to find your 9-digit zip code: Look Up a ZIP Code™.

Application Section	Form Type	Instructions	HRSA/Program Guidelines
			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 NOFO.
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 NOFO.
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 NOFO.
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.
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.	If this attachment is included, it will be 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 period of performance.	Required attachment. Counted in the page limit. Refer to Section 4.1.v of this *Guide* and the NOFO for detailed instructions. Provide table of contents specific to this document only as the first page.

Application Section	Form Type	Instructions	HRSA/Program Guidelines
SF-424 R&R Cumulative Budget	Form	Total cumulative budget.	Required. 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.
Disclosure of Lobbying Activities (SF-LLL)	Form	Supports structured data for lobbying activities.	Not counted in the page limit.
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. Unless the NOFO says otherwise, attachments are counted in the page limit.

- To ensure that attachments are organized and printed in a consistent manner, follow the order provided in the NOFO. Note that these instructions may vary across programs.
- Evidence of non-profit status and invention-related documents, if requested, must be provided in the ATTACHMENTS 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 NOFO.
- 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 NOFO

4.4. Application Page Limit

The total of uploaded attachment pages that count against the page limit shall be no more than the page limit specified in Section IV. 2. of the NOFO when printed by HRSA.

Forms that DO NOT count in the Page Limit

- Standard OMB-approved forms included in the workspace application package **do not** count in the page limit. The abstract is the standard form (SF) "Project_Abstract Summary." It **does not** count in the page limit.
- The Indirect Cost Rate Agreement **does not** count in the page limit.
- The proof of non-profit status (if applicable) **does not** count in the page limit.

If there are other attachments that do not count against the page limit, this will be clearly denoted in the NOFO's Section IV.2.v. or vi. Attachments.

If you use an OMB-approved form that is not included in the workspace application package for your NOFO, it will count against the page limit. Therefore, we strongly recommend you use Grants.gov workspace forms associated with your NOFO to avoid exceeding the page limit.

- HRSA will redact any pages considered over the page limit. The redacted copy of the application will move forward to the objective review committee.

It is important to ensure your application does not exceed the specified page limit.

Applications must be complete and validated by Grants.gov under the funding opportunity number before the deadline.

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

4.5. Submission Dates and Times

Letter of Intent to Apply (ONLY if requested on the cover and in Section IV.7. of the NOFO)
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. HRSA will not acknowledge receipt of letters of intent.

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

HRSA Digital Services Operation (DSO)
Use the HRSA opportunity number as email subject (HRSA-##-###)
HRSADSO@hrsa.gov

Application Due Date

The due date for applications is *11:59 p.m. ET* on the date listed in Section IV.4. Submission Dates and Times in the NOFO, unless otherwise noted. Applications completed online are considered formally submitted when the application has been successfully transmitted electronically to the correct funding opportunity 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, an application is submitted more than once before the application due date, HRSA will only accept and review your **last** validated electronic submission, under the correct funding opportunity number, before the Grants.gov application due date as the final and only acceptable application. Applications submitted under the wrong funding opportunity number may be deemed non-responsive; refer to section 3.6 for more guidance. 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, we urge you to submit your application **at least 3 calendar days before** 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 webpage can be accessed at: Apply For A Grant.

In addition, you can access a concise resource offering tips for writing proposals for HHS grants and cooperative agreements at Tips for Preparing Grant Proposals.

4.8. Withdrawing an Application

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

5. PROCESS OVERVIEW

5.1. Competing Applications through Grants.gov Using Workspace

The process for submitting a competing application through Grants.gov using workspace is as follows:

1) HRSA posts all competing NOFOs on Grants.gov.
2) In order to apply for a HRSA award, you must complete the Grants.gov registration process. See Section 3 for more details.
3) Once the NOFO is available, you should search for the funding opportunity in Grants.gov by clicking the SEARCH GRANTS tab, entering the funding opportunity number (HRSA-##-####) and then selecting the funding opportunity or clicking the APPLICANTS tab and then clicking on *How to Apply for Grants*.
4) Create a workspace package. The NOFO, accessible via the instructions link, contains critical application instructions. Make note of the funding opportunity number.
5) Add workspace participants, complete the workspace package, check for errors, and notify the AOR the application is ready for submission.
6) Submit the application package through Grants.gov.
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 has been validated under the correct funding opportunity number.
8) Once Grants.gov validates your application, you may track the status of the application within HRSA by using the "Track Your Application" widget, now available on HRSA's website. 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 NOFO, including programmatic, budgetary, and grants management compliance. Applications that pass the initial HRSA completeness and 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 NOFO.

All incomplete, ineligible, or otherwise non-compliant applications, and applications determined to be non-responsive to NOFO 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, HRSA will advise applicants by email through the EHBs (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 HRSA 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 process provides an objective evaluation of applications to the individuals 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 NOFO.

Applications that pass the initial HRSA completeness and eligibility screening will be reviewed and rated by a panel based on the program elements and review criteria presented in the NOFO. 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.

HRSA has procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which each application will be reviewed. HRSA has indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. See the review criteria outlined with specific detail and scoring points in the NOFOs.

Funding factors may be applied during the objective review process or in the selection process. Funding factors are addressed in the NOFO, 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 or HRSA staff determine if you've met the funding factor. The NOFO 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 NOFO.

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 funds may be requested from HRSA. Until an awarding office has issued an NOA for the initial budget period, any costs you incur for the project are incurred at your 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 period of performance for which support is contemplated. Signed by the Grants Management Officer (GMO), it is sent to the recipient's 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, HRSA will issue the NOA before the start date of the award as listed in Section V.4 of the NOFO.

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.

Registering in ID.me for Payment Management System (PMS) Access

If you receive an NOA and accept the award, you will need to create an account with ID.me to access HHS' PMS system. PMS is the tool used for managing award payments. This is a **new** requirement that improves identity assurance since it enables multi-factor authentication. For more information, visit the PMS website.

6. REPORTING REQUIREMENTS

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

a. Audit Requirements
Comply with audit requirements of 45 CFR part 75, subpart F. Information on audits can be found on the Internet.

b. Status Reports

1) **Federal Financial Report**. The Federal Financial Report (SF-425) is required. The report is an accounting of expenditures under the project that year. Financial reports must be submitted electronically. Visit Reporting Requirements | HRSA. More specific information will be included in the NOA.

2) **Progress Report(s).** The recipient must submit a progress report to HRSA on a quarterly, semi-annual, or annual basis (as specified in the NOFO) or condition of the award. For multi-year awards, submission and HRSA approval of recipient progress report(s) triggers the budget period renewal and release of subsequent year funds. More information will be provided in the NOA.

3) **Final Report.** A final report is due within 90 calendar days after the period of performance 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 recipient achieved the mission, goal and strategies outlined in the program; recipient objectives and accomplishments; barriers encountered; and responses to summary questions regarding the recipient's overall experiences during the entire period of performance. Recipients must submit the final report online in the HRSA EHBs system.

4) **Tangible Personal Property Report**. If applicable, the recipient must submit the Tangible Personal Property Report (SF-428) and any related forms within 90 calendar days after the period of performance ends. Recipients 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 NOFO**.

c. Transparency Act Reporting Requirements

New awards ("Type 1"[6]) 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 period of performance and so include all subsequent award actions to aforementioned HRSA grants and cooperative agreement awards (e.g., competing continuation ("Type 2"), non-competing continuation ("Type 5"), 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 Requirements for Federal Funding Accountability and Transparency Act Implementation).

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

Contact Grants.gov 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 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. 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 website, visit Grants.gov Support. You can also visit the Grants.gov Self-Service Knowledge Base for answers to commonly asked questions.

[6] Part of a coding system HRSA uses to make distinctions between awards. The award type is the first digit of the "Award No." as indicated on the Notice of Award (NOA).

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 Adobe Software Compatibility.

8.1.2. 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. You can find these applications at GRANTS.GOV Online User Guide. 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.

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

Yes

8.2. Application Receipt FAQs

8.2.1. When do I need to submit my application?

Generally, applications must be submitted and validated via Grants.gov by 11:59 p.m. ET on the due date, however the time may vary. You should refer to the NOFO 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. HRSA strongly suggests submitting applications to Grants.gov **at least 3 calendar days before** the deadline to allow for any unforeseen circumstances.

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. 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 before transmission to HRSA 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, HRSA will download the application 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 opportunity number, along with the correct award number (if applicable) and recipient/applicant organization. This may take up to 3 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 DGMO at HRSA**, within 5 calendar days from the closing date, via email at ApplicationWaivers@hrsa.gov and provide a detailed explanation. Your email must include the HRSA funding opportunity number, the name, address, and telephone number of the organization, the organization's UEI 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
	"Agency Tracking Number Assignment"	Within 3 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, visit Frequently Asked Questions by Applicants.

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, visit Training Resources and Videos for Grants.gov.

8.5. Application Completeness Checklist

- ❑ Have I read the NOFO and this *R&R Application Guide* thoroughly?
- ❑ Is my organization eligible to apply for the funding opportunity?
- ❑ 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 NOFO?
- ❑ Have I ensured my application does not exceed the funding ceiling amount specified in Section III of the NOFO?
- ❑ Have I completed all forms and attachments as requested in Section IV of the NOFO and this *Guide*?
- ❑ Have I ensured my application does not exceed the page limit, if applicable,

specified in the NOFO?
- ❑ Will I apply **at least 3 calendar days before** 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

Refer to Section VIII of the NOFO for additional information/resources (e.g., TA calls/webinars, related programs, useful website addresses).

9. TECHNICAL ASSISTANCE RESOURCES

HRSA's Apply for a Grant TA webpageis a one-stop shop for potential applicants on how to apply for HRSA funding.

APPENDIX: Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy

1. Introduction

A Protection of Human Subjects section of the Research Plan is required for all applications proposing human subjects research 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.

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 scenarios. Determine which scenario the proposed research falls into, then use the specific instructions applicable to that scenario in Section 3 of this document. Where appropriate, Section 3 also provides instructions on addressing the Inclusion of Sex/Gender and Racial/Ethnic Groups, the Inclusion Enrollment Report(s), and the Inclusion of Children. See the Glossary for definitions related to human subjects research. Section 5 includes descriptions of and links to the HHS Human Subjects Protections regulations that apply to clinical research.

For all scenarios, you must provide sufficient information to allow reviews to determine if the designation of human subjects involvement is appropriate. The proposed research must meet all the requirements of applicable HHS policies for the protection of human subjects from research risks, data and safety monitoring (when applicable), and for the inclusion of sex/gender and racial/ethnic groups, and children and reporting of enrollment data for subjects in clinical research (see the Glossary for definition).

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

While this information is written primarily for competing applications, guidance here may also be applicable to interim progress reports.

2. Scenarios

Scenario A. No Human Subjects Research

If no human subjects research is proposed in the application, you will have designated "No" in response to Human Subjects Research in Item 1 on the SF-424 RESEARCH & RELATED Other Project Information form. 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.

Scenario B. Non-Exempt Human Subjects Research

If research involving human subjects that does not meet the exemption categories is anticipated to take place under the award, on the SF-424 RESEARCH & RELATED Other Project Information form you will have designated "Yes" in response to "Are Human Subjects Involved?" and "No" in response to "Is the Project Exempt from Federal regulations?" You must provide a complete Protection of Human Subjects section.

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 (45 CFR § 46.101(b)) (see the Glossary for a detailed description of the exemptions), on the SF-424 RESEARCH & RELATED Other Project Information form you will have designated "Yes" in response to "Are Human Subjects Involved?", "Yes" to "Is the Project Exempt from Federal regulations?", and marked the appropriate exemption number. "NA" should be entered for the Human Subject Assurance Number since no assurance number is required for exempt research.

If you are not sure whether your proposed research qualifies for an exemption, consult with the Office for Human Research Protections (OHRP), Department of Health and Human Services by accessing their Web site Office for Human Research Protections for guidance and more information.

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 § 46.118), if using the SF-424 RESEARCH & RELATED Other Project Information form you will have designated "Yes" in response to "Are Human Subjects Involved?" and, if applicable, "Yes" to "Is the Project Exempt from Federal regulations?" and marked the appropriate exemption number. Examples of delayed-onset of human subjects research include:

- Human subjects research design is dependent upon the completion of animal or other studies; or
- Human subjects research protocols to be conducted will be determined at a later time after award (often defined by a NOFO).

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 phase I, II, or III clinical trial during the period of performance that is characterized to include:

a) Prospective assignment of human subjects;
b) One or more interventions, and;
c) Identification of one or more health-related biomedical or behavioral outcomes

If using the SF-424 RESEARCH & RELATED Other Project Information form, you will have designated **"**Yes**"** in response to "Are Human Subjects Involved?", and "No" to "Is the Project Exempt from Federal regulations?"

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	N/A
Clinical Trial	N/A

Instructions and Required Information

If proposed studies involve the use of human data or biological specimens, provide an explanation of why the proposed studies do not constitute research involving human

subjects. In the application narrative (Section H Protection of Human Subjects), include the following statement below the section heading: "No Human Subjects Research is proposed in this application" plus any justification as needed.

For studies involving human data or biological specimens, explanation should include: a description of the source of the data/biospecimens; whether they will be collected specifically for this study or were collected for another purpose; what identifiers will be associated with the human specimens and data and who has access to subject identities; 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 (see the Glossary). 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 (Coded Private Information or Specimens Use in Research, Guidance (2008)).

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 limit applies to this section of the application, be succinct. In the application narrative (Section H Protection of Human Subjects), create a subheading for each required topic.

Follow the instructions that are identified for each of the following topics and provide the required information:

- **Protection of Human Subjects** - Section 4.1 - 4.1.4
- **Inclusion of Sex/Gender and Racial/Ethnic Groups**- Section 4.2
- **Inclusion Enrollment Reports(s)** - refer to NOFO for details
- **Inclusion of Children** - Section 4.3

If the research involves more than one protocol or subproject, provide the information identified above for each unique protocol or project.

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	No

Instructions and Required Information

Although no specific page limit applies to this section of the application, be succinct. A detailed description of the exemptions can be found in the Glossary.

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

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

- **Protection of Human Subjects** - Include the following statement: "This Human Subjects Research falls under Exemption(s) …" Clearly identify which exemption(s) (1, 2, 3, 4*, 5, or 6) you are claiming and justify why the research meets the criteria for the exemption(s) that you have claimed. This justification should explain how the proposed research meets the criteria for the exemption claimed and should not merely repeat the criteria or definitions themselves.
- **Inclusion of Sex/Gender and Racial/Ethnic Groups*** - Section 4.2
- **Inclusion Enrollment Report** -refer to NOFO for details
- **Inclusion of Children** - Section 4.3

*NOTE: If all of the proposed research meets the criteria for Exemption 4, then the requirements for inclusion of sex/gender and racial/ethnic groups, 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 made by the institution after award, research networks or multi-site studies where protocols to be conducted are determined after all sites have been selected, or projects in which the involvement of human subjects depends upon initial work in the award such as completion of instruments, animal studies, or purification of compounds.

In the application narrative (Section H Protection of Human Subjects), create a subheading for each required topic.

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 - 4.1.4
- **Inclusion of Sex/Gender and Racial/Ethnic Groups** - Section 4.2
- **Inclusion Enrollment Report(s)** - refer to NOFO for details
- **Inclusion of Children** - Section 4.3

If the research will include a clinical trial, characterized to include (1) prospective assignment of one or more human subjects; (2) one or more intervention (which can include placebo or other control), and; (3) evaluation of the effects of the intervention on one or more health-related biomedical or behavioral outcomes, also include the following topics.

- **Data and Safety Monitoring Plan** - Section 4.1.5
- **ClinicalTrials.gov Requirements** - Section 4.1.6, if applicable

If an award is made, prior to the involvement of human subjects, the grantee 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), Human Subjects Assurance number, 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.

Under no circumstance may human subjects be involved in research until approval is granted by the awarding entity, and certification of IRB approval (or justification for

exemption) has been accepted by the agency. Inclusion plans and inclusion enrollment report(s) must also be submitted to the agency prior to starting human subjects studies.

Scenario E: Clinical Trial

Criteria

Human Subjects Research	Yes
Exemption	No
Clinical Trial	Yes

Instructions and Required Information

In the application narrative (Section H Protection of Human Subjects), include the following statement below the heading: "This Human Subjects Research meets the definition of a clinical trial." (See definition of "clinical trial" in the Glossary.) Additionally, create a subheading for each required topic discussed below. Provide the required information for each of the following topics below:

For each clinical trial proposed, follow the instructions that are identified for each of the following topics and provide the required information:

- **Protection of Human Subjects -** Section 4.1 - 4.1.4
- **Data and Safety Monitoring –** Section 4.1.5
- **ClinicalTrials.gov Requirements** - Section 4.1.6, if applicable
- **Inclusion of Sex/Gender and Racial/Ethnic Groups**- Section 4.2
- **Inclusion Enrollment Report(s)** - refer to NOFO for details
- **Inclusion of Children** - Section 4.3

If the research involves more than one trial/protocol or subproject, provide the information identified above for each unique protocol or project.

4. Instructions Pertaining to Non-Exempt Human Subjects Research

This information will be placed in your application narrative (Section H Protection of Human Subjects). Although no specific page limit 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 Sections 4.1-4.4 below. If your research includes a clinical trial, include a separate document entitled "Data and Safety Monitoring Plan" and follow the instructions in Section 4.1.5 below. If your research includes a Phase III Clinical Trial, also follow the additional instructions in Section 4.2.1 below.

4.1 Protection of Human Subjects

4.1.1 Risks to Human Subjects

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

- Describe and justify the proposed involvement of human subjects in the work outlined in the Research Strategy section.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status, if relevant.
- Describe and justify the sampling plan, including retention strategies and the criteria for inclusion or exclusion of any subpopulation.
- If relevant, 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, provide details about all planned interventions such as 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 will be collected, managed, and protected, as well as whether any individually identifiable private information will be collected specifically for the proposed research project.

c) Potential Risks

- Describe all the potential risks to subjects posed by participation in the research (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. When alternative treatments or procedures are possible, the rationale for the proposed approach should be clear.

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. When appropriate, describe how potential adult subjects' capacity to consent will be determined and plans for obtaining consent from a legally authorized representative for adult subjects not able to 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 HRSA unless requested.

b) Protections Against Risk

- Describe planned procedures for protecting against or minimizing all potential risks identified, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.
- Describe how proposed research involving vulnerable populations meets the additional regulatory requirements described in the HHS regulations, subparts B, C, or D. Refer to HHS regulations, and OHRP guidance:
    - Additional Protections for Pregnant Women, Human Fetuses and Neonates: Subpart B - Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
    - Additional Protections for Prisoners: Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
    - OHRP Subpart C Guidance: Prisoner Involvement in Research (2003)
    - Additional Protections for Children: Code of Federal Regulations Title 45 Public Welfare DHHS Part 46 Protection of Human Subjects
    - OHRP Subpart D Guidance: Subpart D - Additional Protections for Children Involved as Subjects in Research
- 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 (see definition of "clinical trial" in the Glossary) must include a separate attachment describing the plan for data and safety monitoring of the clinical trials and adverse event reporting to the IRB, the Data and Safety Monitoring Board (DSMB) (if one has been established for the trial), HRSA and others, as appropriate, to ensure the safety of subjects (see Section 4.1.5 below).

- Where appropriate, describe plans for handling incidental findings that may be uncovered as a result of the research, such as incidental findings from research imaging, results of screening tests, or misattributed paternity.

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.

4.1.3 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.
- Please note that financial compensation of subjects should not be presented as a benefit of participation in research.

4.1.4 Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge 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.

4.1.5 Data and Safety Monitoring Plan

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

If the proposed research includes a clinical trial, create a heading in Section H Protection of Human Subjects entitled "Data and Safety Monitoring Plan." Provide a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial and its size and complexity. You must provide a description of the DSMP that you are proposing to establish for each clinical trial proposed, including:

- The overall framework for safety monitoring and what information will be monitored.
- The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable).
- The process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events, and Unanticipated Problems (UPs), will be managed and reported as required to the

Institutional Review Board (IRB), the person or group responsible for monitoring, and HRSA.

- The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the monitoring plan will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible. These include, but are not limited to, monitoring by a:
    - Project Director (PD)/Principal Investigator (PI): While the PD/PI must ensure that the trial is conducted according to the protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PD/PI to also be responsible for carrying out the DSMP.
    - Independent safety monitor/Designated medical monitor: a physician or other expert who is independent of the study.
    - Independent Monitoring Committee or Safety Monitoring Committee: A small group of independent investigators and biostatisticians.
    - Data and Safety Monitoring Board (DSMB): a formal independent board of experts including investigators and biostatisticians. As noted in Section 5.3, PHS requires the establishment of 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.
    - If a DSMB is used, please describe the general composition of the Board without naming specific individuals.

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 "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 and results reporting for ALL clinical trials whether or not registration is required under the FDAAA. On January 28, 2015, NCI published a policy requiring the reporting of final trial results in a publicly accessible manner within 12 months of the trial's primary completion date.

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 (example: R40MC#####).

Registration is accomplished at the ClinicalTrials.gov Protocol Registration System Information Web site. A unique identifier called an NCT number, or ClinicalTrials.gov registry number, will be generated during the registration process. This number should be included in all Progress Reports and publications.

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 a HRSA 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 results reporting under FDAAA, provide the NCT number/s in the human subjects section of the Research Plan under a section heading entitled 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), or
2) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or recipient (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). See PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)(ix).

For the complete statutory definitions of "responsible party" and "applicable clinical trial," refer to Elaboration of Definitions of Responsible Party and Applicable Clinical Trial.

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

4.2 Inclusion of Sex/Gender and Racial Ethnic Groups

In Section I Targeted Enrollment of the application narrative, create a section subheading entitled "Inclusion of Sex/Gender and Racial/Ethnic Groups". Although no

specific page limits apply to this section of the application, be succinct. This section does not take the place of considering relevant biological variables (such as sex) in the research strategy. The PHS Policy on the Inclusion of Sex/Gender and Racial/Ethnic Groups in Clinical Research is described and referenced in Section 5.6.

Scientific Review Groups (ie, the Objective Review Committees at HRSA) will assess each application as being acceptable or unacceptable with regard to the scientifically justified inclusion (or exclusion) based on sex/gender, race, and ethnicity in clinical research (see the Glossary for definition). This section is required for all studies meeting the definition for clinical research, not just clinical trials. It is important to provide a detailed plan of who will be included (and/or excluded) and how the distributions of individuals on the basis of sex/gender, race, and ethnicity are justified in the context of the scientific goals of the application. Simply stating that certain individuals will not be excluded or that individuals of any sex/gender or race/ethnicity are eligible is not sufficient. Details about why the individuals are the appropriate individuals to accomplish the scientific goals of the study should be provided.

In this section, address, at a minimum, the following four points:

1) Describe the planned distribution of subjects by sex/gender, race, and ethnicity for each proposed study.
2) Describe the subject selection criteria and rationale for selection of sex/gender, racial, and 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 understudy.
3) Provide a compelling rationale for proposed sample specifically addressing exclusion of any sex/gender, racial, or ethnic group that comprises the population under study.
4) Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members as subjects. This is particularly important if difficulty recruiting certain groups is anticipated.

Additional Considerations for justifying inclusion:

There may be reasons why the proposed sample is limited by sex/gender, race, and/or ethnicity. This should be addressed as part of the four points detailed above.

- Inclusion of certain individuals would be inappropriate with respect to their health;
- The research question addressed is only relevant to certain groups or there is a gap in the research area;
- Evidence from prior research strongly demonstrates no difference on the basis of sex/gender, race, and/or ethnicity;
- Sufficient data already exist with regard to the outcome of comparable studies in the excluded group(s)and duplication is not needed in this study;

- A certain group or groups is excluded or severely limited because the purpose of the research constrains the applicant's selection of study subjects (e.g., uniquely valuable stored specimens or existing datasets are limited by sex/gender, race, and/or ethnicity; 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); and/or
- Representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete sex/gender documentation are used), and this does not compromise the scientific objectives of the research.
- In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups. This should be considered when developing outreach plans. Establishing collaborations or other arrangements to recruit may be necessary.
- Additional guidance for research utilizing existing datasets or resources:
    - Inclusion must be addressed when conducting clinical research, even if the samples or data have already been collected as part of a different study. Details about the sex/gender, race, and ethnicity composition of the existing dataset/resource should be provided and justified as appropriate to the scientific goals of the proposed study.
    - For the purposes of inclusion policy, an existing dataset may be constructed of different types of data including but not limited to survey data, demographic information, health information, genomic information, etc. Also included would be data to be derived from existing samples of cells, tissues, or other types of materials that may have been previously collected for a different purpose or research question but will now be used to answer a new research question. In general, these will be studies meeting the definition for clinical research with a prospective plan to analyze existing data and/or derive data from an existing resource and where no ongoing or future contact with participants is anticipated.

4.2.1 Additional Instructions and Requirements When Large Clinical Trials Are Proposed

If the proposed research includes a large Clinical Trial (ie, a randomized controlled trial with several hundred or several thousand participants), the section on Inclusion of Sex/Gender and Racial/Ethnic Groups also MUST address plans for how sex/gender, race, and ethnicity will be taken into consideration in the design and valid analysis of the trial. Valid analysis means an unbiased assessment which will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect.

Scientific Review Groups (ie, the Objective Review Committees at HRSA) will assess each application as being acceptable or unacceptable with regard to the scientifically

justified inclusion plans, including these additional requirements for Phase III clinical trials.

Applicants should address the following issues for ensuring valid analyses:

- Inclusive eligibility criteria – in general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups;
- Allocation of study participants rom different sexes/genders and racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization;
- Unbiased evaluation of the outcome(s) of study participants; and
- Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects by sex/gender, race, and/or ethnicity, particularly if prior evidence strongly suggests that differences exist.

Applicants also should address whether they plan to test or not test for differences in effect among sex/gender, racial, and/or ethnic groups and why that is or is not appropriate. This may include supporting evidence and/or data derived from animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies as well as observational, natural history, epidemiology and/or other relevant studies. Additional factors may include planned primary and secondary outcomes and whether there are previous studies that support or negate the likelihood of differences between groups.

The plans must include selection and discussion of one of the following analysis plans:

- Plans to conduct analyses to detect significant differences in intervention effect among sex/gender, racial, and/or ethnic subgroups when prior studies strongly support these significant differences among one or more subgroups, or
- Plans to include and analyze sex/gender, racial, and/or ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender, racial, and ethnic groups is not required as subject selection criteria, but inclusion is encouraged), or
- Plans to conduct valid analyses of the intervention effect in sex/gender, racial, and/or ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect among subgroups.

4.3 Inclusion of Children

Create a subsection entitled “Inclusion of Children” and place it immediately following the subsection on the Inclusion of Sex/Gender and Racial/Ethnic Groups. Although no specific page limits apply to this section of the application, be succinct. The Policy on Inclusion of Children is referenced and described in Section 5.8 for inclusion in the application narrative section. For the purpose of implementing these guidelines, a *child* is defined as an individual under the age of 18 years.

Scientific Review Groups (ie, the Objective Review Committees at HRSA) 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. This section is required for all studies meeting the definition for clinical research, not just clinical trials. It is important to provide a detailed plan of who will be included (and/or excluded) based on age. Details about why the individuals in the given age/age range are the appropriate individuals to accomplish the scientific goals of the study should be provided.

Instructions for this item of the Research Plan, **including addressing the following points**:

- Describe the age(s) or age range of all individuals to be included in the proposed study.
- Specifically discuss whether children under the age of 18 (as a whole or a subset of individuals under 18) will be included or excluded.
- 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.
- 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, individuals under 18 are defined as a child; however, exclusion of any specific age or age range group 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:

- The research topic to be studied is not relevant to children.
- Laws or regulations bar the inclusion of children in the research.
- 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.
- A separate, age-specific study in children is warranted and preferable. Examples include:
  - 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
    - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
    - 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.
- 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.
- 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).
- Other special cases can be justified by the investigator and assessed by the review group and HRSA to determine if acceptable.

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, 45 CFR part 46, 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 recipient 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 Federal-wide Assurance (FWA) with the Office for Human Research Protections (OHRP), and establish appropriate policies and procedures for the protection of human subjects. These regulations are available from OHRP, Department of Health and Human Services, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD; telephone: 1-866-447-4777 (toll-free) or (240) 453-6900; email:

ohrp@hhs.gov. In general, OHRP considers organizations that receive direct support from HHS for the conduct of non-exempt 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: Engagement of Institutions in Human Subjects Research (2008)). When a research project is conducted by multiple organizations, each organization that is engaged in non-exempt human subjects research must hold an FWA and comply with the regulations at 45 CFR part 46.

Non-exempt research involving human subjects may only be conducted under an 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. Foreign applicant organizations must also comply with the provisions of the regulations.

Under HHS regulations to protect human subjects, certain research activities are exempt. 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 sex/gender and racial/ethnic groups, and children in the study design.

Regulations of the Food and Drug Administration (21 CFR part 50, 21 CFR part 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 CFR - Code of Federal Regulations Title 21. 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 may apply to 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.” Research involving the use of coded private information or biological specimens may not constitute human subjects research. Refer to the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens to clarify when such research is or is not research involving human subjects: Coded Private Information or Specimens Use in Research, Guidance (2008).

The HHS regulations require HRSA to evaluate all applications and proposals involving human subjects (45 CFR § 46.120). This independent evaluation is conducted 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.

5.1.1 Research Involving the Use of Newborn Blood Spots

Federally funded research using newborn dried blood spots collected on or after March 18, 2015, is considered to be non-exempt human subjects research, and therefore, must follow the HHS protection of human subjects regulations at 45 CFR part 46.

Grant applications submitted to HRSA that will use such materials in research should be designated as non-exempt human subjects research and include a complete Protection of Human Subjects section per these instructions including plans for inclusion on the basis of sex/gender, race, ethnicity, and age.

Such applications that are funded by HRSA must comply with all the relevant federal regulatory and policy requirements for human subjects research including the requirement that the recipient institution (and all engaged institutions) have a Federal-wide Assurance (FWA) from OHRP and certification of IRB approval of the proposed research.

Parental permission must have been obtained in order to use newborn dried blood spots collected on or after March 18, 2015, in HRSA-funded research. Waiver of parental permission for such research is not permitted under this legislation.

Section 12 of the Newborn Screening Saves Lives Reauthorization Act of 2014 applies to use of newborn dried blood spots in HHS-funded research. Research funded solely by state or private entities does not constitute “federally funded research” and is not subject to Section 12 of the new law. Non-identifiable newborn dried blood spots collected prior to March 18, 2015, may continue to be used in NIH-funded research without parental permission, and this activity would continue to be considered research that does not involve human subjects under the current human subjects regulations.

5.2 Vulnerable Populations

Investigators who conduct research involving pregnant women, human fetuses and neonates, prisoners (including subjects who become prisoners after the research has started), or children, must follow the provisions of the regulations in subparts B, C, or 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.

Exemptions 1-6 (see Exemptions in the Glossary) 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(es) not participate in the activities being observed.

5.3 Data and Safety Monitoring Plans for Clinical Trials

For each proposed clinical trial (See definition of "clinical trial" in the Glossary), a data and safety monitoring plan is required 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, HRSA, and other appropriate offices or agencies. This policy requirement is in addition to any monitoring requirements imposed by 45 CFR part 46.

The establishment of a Data and Safety Monitoring Board (DSMB) is specifically required 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, individual IRBs and to the DSMB (if one has been established for the trial) or other monitoring entity 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 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 (if it has not already been approved). See Office for Human Research Protections to register an IRB. Certification of IRB approval must be sent to the Grants Management Office identified in the notice requesting documentation.

Because HHS human subject regulations at 45 CFR § 46.103(f) require that each application for HHS-supported non-exempt human subject research be reviewed and approved by an IRB (see also IRB Review of Applications for HHS Support (2000)) the date of approval of the application must 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 that is not using a single IRB of record, the primary grantee is expected to collect the certification from each subrecipient.

Recipients involved in multi-site research may agree to rely on a single IRB of record. The IRB of record must have an assurance with OHRP. Following OHRP guidance, HRSA expects that such reliance arrangements will be documented through the signing of an IRB Authorization Agreement.

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 any research activities involving human subjects are initiated. It is the responsibility of the PD/PI and the applicant organization to submit the follow-up documentation.

IRB approval must be dated within the last year to be valid. If more than a year will have elapsed between the initial IRB review date and the anticipated award date, HRSA shall require re-review by the IRB prior to award.

Continuing IRB review of ongoing human subjects research is also required by 45 CFR § 46.109(e). A progress report for continuation support should not be submitted until certification of annual IRB review has been obtained. The recipient institution must track and document IRB approval for all components of an award that involve human subjects. Progress reports should report the most recent IRB approval date for any component which the IRB has approved.

5.5 Required Education in the Protection of Human Research Participants

HRSA requires education on the protection of human research participants for all individuals identified in applications as senior/key personnel who will be involved in the design or conduct of human subjects research, before funds are awarded for applications or contract proposals involving human subjects. For information relating to this requirement, see the following notices NOTICE: OD-00-039 and NOTICE: NOT-OD-01-061, and Frequently Asked Questions at: Frequently Asked Questions on Requirements for Education. Prior to initiating any research activities involving human subjects, institutions will be required to certify to HRSA that all senior/key personnel involved in the design or conduct of human subjects research have completed this educational requirement. Although HRSA does not endorse specific programs, curricula are available to provide guidance and can be modified to provide training in this area. For information on facilitating education and developing curricula, see Bioethics Interest Group. Also, NIH has a free tutorial on human subjects protection that can be used to meet this educational requirement: see NIH: Resources.

5.6 Policy on the Inclusion of Sex/Gender and Racial/Ethnic Groups in Clinical Research

PHS policy requires that all PHS-supported biomedical and behavioral research projects involving clinical research include diverse sex/gender and racial/ethnic minority populations 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 Associate Administrator or Office Director, upon the recommendation of a HRSA program office 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. This policy applies to research subjects of all ages.

Representation of diverse racial/ethnic minority populations, as well as sex/gender, 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, race, and ethnicity, and provide a rationale for selection of subjects. It is important to justify the proposed sample on the basis of sex/gender, race, and ethnicity in the context of the scientific goals of the proposed study(s) with discussion of the demographics of the population under study and/or who is at risk for the disease/condition. Such a plan should contain a description of the proposed outreach programs for recruiting women and racial/ethnic minorities as participants.

In addition, as detailed in Section 4.2.1 of these instructions, when conducting a clinical trial, there are additional requirements and considerations related to valid analysis to explore differences on the basis of sex/gender, race, and ethnicity.

5.7 PHS Policy on Reporting Race and Ethnicity Data for 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: Race and Ethnic Standards for Federal Statistics.

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). 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. Federal agencies will not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

Collection of this information and use of these categories is required for research that meets the definition of clinical research. The collection of greater detail is encouraged, for example on racial or ethnic subpopulations. However, any collection that uses more detail must be designed in a way that data can be aggregated into these minimally required OMB categories. Use self-report or self-identification to collect this information from subjects by asking two separate questions – one on ethnicity and one on race.

Collect ethnicity information first, followed by the question on race and provide participants with the option to select more than one racial category. Participants also have the option not to identify. When feasible, HRSA encourages investigators to include information about individuals who select more than one racial category and consider that data in their analyses. Participants who self-identify with more than one racial category should be reported under the "More than one race" category of the report. 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, 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 socio-cultural implications related to the scientific question under study.

5.8 PHS Policy on Inclusion of Children

PHS policy requires that children (i.e., individuals under the age of 18) must be included in all clinical research conducted or supported by HRSA unless there are clear and compelling reasons not to include them. Therefore, applications proposing clinical research must include a description of plans for including children. If children (or a subset of children) will be excluded from the research, the application must include an acceptable justification for the exclusion. For additional details and guidance, please refer to Section 4.3 of these instructions.

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.

5.9 Research on Transplantation of Human Fetal Tissue

In signing the application Face Page or checking the "I agree" box on line 17 of the SF-424 R&R Cover Form, the Authorized Organization Representative of the applicant organization certifies that if research on the transplantation of human fetal tissue is conducted, the applicant organization will make available, for audit by the Secretary, HHS, the physician statements and informed consents required by section 498A (b)(2) and (c) of the Public Health Service Act, 42 U.S.C. 289g (b)(2) and (c), or ensure HHS access to those records, if maintained by an entity other than the applicant organization.

5.10 Research Using Human Embryonic Stem Cells

In signing the application Face Page or checking the "I agree" box on line 17 of the SF-424 R&R Cover Form, the Authorized Organization Representative of the applicant organization certifies that if research using human embryonic stem cells is proposed, the applicant organization will identify human embryonic stem cells (hESCs) to be used from the NIH Registry (NIH Human Embryonic Stem Cell Registry), or, if a specific cell line cannot be referenced at the time of application, certify that one from the NIH Registry will be used, in accord with the NIH Guidelines on Human Stem Cell Research. The Authorized Organization Representative further certifies that the hESCs will be used in accordance with any restrictions associated with the line as cited on the Registry (Notice Number: NOT-OD-10-029 Clarification of Terms and Conditions of Awards using Human Embryonic Stem Cells). See NIH: Stem Cell Information for additional information on stem cells, federal policy statements, and guidelines on federally funded stem cell research.

5.11 ClinicalTrials.gov Requirements

In signing the application Face Page or checking the "I agree" box on line 17 of the SF-424 R&R Cover Form, the Authorized Organization Representative of the applicant organization certifies that if the research is 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 (Section 4.1.6).