

**U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Minority Health**

Health Equity Data Access Program

Notice of Funding Opportunity Type: New

Funding Opportunity Award Type: Grant

Notice of Funding Opportunity Number: CMS-2L2-23-001

Federal Assistance Listings Number (CFDA): 93.695

Notice of Funding Opportunity Posting Date: June 29, 2023

Applicable Dates:

Letter of Intent to Apply Due Date: July 16, 2023

Electronic Application Due Date: August 15, 2023, 3:00 pm Eastern Standard Time

Anticipated Issuance Notice(s) of Award: September 15, 2023

Anticipated Period of Performance: September 15, 2023 through September 14, 2026

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Executive Summary

The Health Equity Data Access program (HEDAP) provides funding for three (3) “seats” in the [CMS Virtual Research Data Center \(VRDC\)](#). The VRDC assists researchers in gaining access to CMS restricted data for minority health research. Seats, in this context are defined as an individual user with VRDC access. These researchers will conduct health services research focusing on, but not limited to, racial and ethnic minority groups; people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; individuals residing in rural areas; and individuals adversely affected by persistent poverty or inequality. The HEDAP supports specific applied research projects that relate to creative and innovative methods utilizing CMS data to identify, document, assess, and evaluate health disparities among Medicare and Medicaid and CHIP enrollees.

The project should enhance the capacity of the researcher to understand and utilize CMS data in future research projects. Additionally, HEDAP encourages cutting-edge proposals that explore intersectionality. “Intersectionality” [means that people belong to more than one group and, therefore, may have overlapping health and social inequities, as well as overlapping strengths and assets.](#)

Results of the HEDAP will provide CMS and its partners, (e.g. Quality Improvement Organizations, Hospital Engagement Networks, and other stakeholders) with **actionable information** on the subgroups of enrollees. This will aid the efforts of CMS and its agents to identify and eradicate health disparities in underserved populations.

VRDC seat access will be funded for a period of 36 months each, based on the availability of funds.

Item	Description
HHS Awarding Agency	Centers for Medicare & Medicaid Services (CMS)
CMS Awarding Center	CMS Office of Minority Health (OMH)
Notice of Funding Opportunity Title	Health Equity Data Access Program (HEDAP)
Authorization	Section 1110 of the Social Security Act
Federal Assistance Listings Number	93.695
Funding Opportunity Type	New

Funding Opportunity Number	CMS-2L2-23-001
Type of Award	Grant
Type of Competition	Competitive
Letter of Intent	CMS highly recommends that interested applicants submit a Letter of Intent; however, it is not required. See Section C.3 for more information.
Electronic Application Due Date and Time	August 15, 2023 by 3:00 pm EST (Baltimore, MD)
Anticipated Issuance Notice(s) of Award	September 15, 2023
Period of Performance Start Date	September 15, 2023
Period of Performance End Date	September 14, 2026
Anticipated Total Available Funding	\$270,000 (pending the availability of funds)
Estimated Maximum Award Amount	\$90,000
Estimated Maximum Number of Awardees	3

A. Program Description

A1. Purpose

The Centers for Medicare & Medicaid Services (CMS) is announcing the availability of funds under the Health Equity Data Access Program (HEDAP). HEDAP provides funding for three (3) “seats” in the [CMS Virtual Research Data Center \(VRDC\)](#). to allow researchers from institutions of higher education access to CMS restricted data for minority health research. Seats, in this context are defined as an individual user with VRDC access. <https://resdac.org/cms-virtual-research-data-center-vrdc-faqs>

The HEDAP aims to:

- Help researchers gain access to CMS data to conduct health services research focusing on, but not limited to, racial and ethnic minority groups; people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; individuals residing in rural areas; and individuals adversely affected by persistent poverty or inequality.
- Produce specific applied research projects that relate to creative and innovative methods for using CMS data to identify, document, assess, and evaluate health disparities among Medicare, Medicaid and CHIP enrollees.
- Create data driven research that explores, but is not limited to, the relationship between health disparities and:
 - Improving the quality of care
 - Increasing access to care
 - Estimating the economic burden/financial costs of disparities
 - Evaluating the effects of health care delivery system and payment model reforms
 - Exploring disparity sensitive conditions or diseases
 - Strengthening population health

CMS will award HEDAP funds, through a competitive process, to up to three (3) institutions of higher education per cohort. The HEDAP timeline is three (3) years, pending the availability of funds. The award only covers the cost of for access to the VRDC for a three-year period. All research activities as described above must be funded by the recipients except for the access payment granted for the Chronic Conditions Data Warehouse (CCW) data in the VRDC to ResDAC. The parameters of the HEDAP are described throughout this Notice of Funding Opportunity (NOFO).

A2. Authority

This HEDAP is under the authority of Section 1110 of the Social Security Act and is consistent with two executive orders:

- [Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities Through the Federal Government](#)
- [Executive Order 14091: Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government](#)

More information about these Executive Orders may be found via each of the links above.

A3. Background

The HEDAP is part of CMS' efforts to identify and disseminate promising practices for reducing health disparities among racial and ethnic minority groups; people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; individuals residing in rural areas; and individuals adversely affected by persistent poverty or inequality.

The HEDAP supports CMS' mission of achieving health equity for all enrollees by granting researchers access to restricted CMS data to perform health services research focused on reducing disparities for the minority populations identified in Section A4.

Results will provide CMS and HEDAP's recipients with actionable information on the subgroups of people with Medicare, Medicaid, and CHIP. This will aid the efforts of CMS and its agents to identify and eradicate health disparities in underserved populations.

The Chronic Conditions Data Warehouse (CCW) is a database of Medicare and Medicaid data to support research. The Virtual Research Data Center (VRDC) allows for virtual access to the CCW data. Researchers must pay a fee for a "seat" in the VRDC. This grant program funds VRDC seat access for a period of 36 months per seat for up to 3 recipients. The Research Data Assistance Center (ResDAC) is a CMS contractor that provides assistance to academic, non-profit, for-profit, and government researchers interested in CMS data.

<https://resdac.org/#find-cms-data-file>

A4. Program Requirements

The HEDAP requires applicants' research project(s) align with CMS programs and policies as well as [Executive Order 13985- Advancing Racial Equity and Support for Underserved Communities Through the Federal Government](#). Satisfactory progress for selected recipients includes, but is not limited to: quarterly meeting check-ins with CMS OMH; publishing a manuscript based on data access received within the 36 month funding period; presentations based on data access received within the 36 month funding period; completion of a [Disparities Impact Statement](#) in the first 3 months of the funding period; standardized data collection (disability questions per [2011 HHS data standards](#), language preference, gender identity, assigned sex at birth, sexual orientation, and appropriate questions on social determinants of health [e.g. coverage type, transportation, social isolation, health literacy, housing insecurity, food insecurity, etc.]); analysis that includes demographic and social determinants of health (SDOH) data to conduct root cause analysis of disparities and results of solutions that were tested.

As stated above, recipients are required to develop a disparity impact statement within 3 months using local data and input to identify populations at highest risk for health, social, economic, or other disparities such as low health literacy. The disparity impact statement will identify social, policy, historical, and other context associated with root causes and drivers of disparities. It will also provide the framework and plan for ongoing action and accountability, such as program improvement, incorporation of the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care, monitoring and assessment of the impact of the project on the program's equity goals. (See CMS.gov: Quality Improvement & Interventions: Disparity Impact Statement).

Research topics of interest include, but are not limited to, the following two (2) examples:

- To research racial and ethnic minority groups; people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; individuals residing in rural areas; and individuals adversely

affected by persistent poverty or inequality among Medicare, Medicaid and CHIP enrollees.

- The relationship between health disparities and improving the quality of care, increasing access to care, estimating the economic burden/financial costs of disparities, evaluating the effects of health care delivery system and payment model reforms, exploring disparity sensitive conditions or diseases and strengthening population health for all the above-mentioned populations.

Research topics that are not appropriate for this NOFO:

- Genome-Wide Association Studies (GWAS);
- Studies investigating biological mechanisms such as metabolic changes/chronic metabolic diseases on the microenvironment (including immune cells, surrounding blood vessels, soluble factors) in racial/ethnic minorities,
- Studies that do not propose health disparity research; and
- Studies not related to CMS programs as outlined in the Purpose (A1) and Background sections (A3) of this NOFO.

Past research topics include:

- Disparities in surgical care among racial and ethnic minorities in Medicare Accountable Care Organizations (ACOs).
- Disparities in rates of surgical intervention among racial and ethnic minorities in Medicare.
- Do Medicare Accountable Care Organizations reduce disparities after spinal fracture?
- Medicaid payment reform and disparities in cesarean birth and maternal morbidity.
- Cesarean delivery rates and cost of childbirth in a state Medicaid program after implementation of a blended payment policy.
- Accessing mental health care disparities by race and ethnicity, gender, and gender identity.
- Identifying gender minority patients' health and health care needs in administrative claims data.
- Trends in mental health care use in Medicare from 2009 to 2014 by gender minority and disability status.
- Disparities in suicidality by gender identity among Medicare enrollees.
- Impact of the Medicare Shared Saving Program on Utilization of Mental Health and Substance Use Services by Eligibility and Race/Ethnicity.
- Medicaid payment policy and disparities in mental health care among Medicaid and dual eligible enrollees.
- Health disparities in vascular access, peritoneal dialysis access, and kidney transplantation.
- Characterizing disparities in the HIV prevention and care continuum among transgender and cisgender Medicaid & Medicare enrollees.
- Documenting the Health of Aging and Disabled Transgender and Cisgender Medicare Enrollees. 2009 – 2017.
- Value-base purchasing and persons with disabilities.

A5. Technical Assistance and Information for Prospective Applicants

This NOFO encourages research projects that develop and test new methodologies, models, and research interventions and/or technologies focused on specific topics addressing social determinants of health. The availability of beneficiary data through the CMS Chronic Conditions Data Warehouse (CCW) makes it feasible to study factors that contribute to disparities in health outcomes among different racial and ethnic populations enrolled in CMS programs.

Applicants are strongly encouraged to include in their application how they propose to include data analysis by race and ethnicity ([HHS 2011 data standards](#)), disability (HHS 2011 data standards), geographic location (urban/rural), language preference, sexual orientation, gender identity, sex assigned at birth, and/or social determinants of health (e.g. coverage type, transportation, social isolation, health literacy, housing insecurity, food insecurity, socioeconomic status (SES), pollution/toxins, neighborhood safety, and effects of environmental change).

B. Federal Award Information

B1. Total Funding

The total anticipated amount of federal funds available is \$270,000, pending the availability of funds.

B2. Award Amount

Individual fixed amount awards will not exceed \$90,000. The period of performance is a 36-month budget period subject to availability of funds and satisfactory performance by the recipient. The sole purpose of each fixed amount award is to obtain a “seat” in the [CMS Virtual Research Data Center \(VRDC\)](#). This “seat” allows researchers from institutions of higher education access to CMS restricted data for minority health research as described in Section A1. Purpose and A4. Program Requirements.

CMS will release funding in the amount of \$30,000 annually. At the time of award, the recipient will only have access to funds in Year 1 conditional upon any restrictions noted on the Notice of Award for year 1 activities and costs. Funds for Years 2 and 3 will remain restricted. The recipient may not incur costs or drawdown funds for Year 2 and 3 until CMS issues a Notice of Award to release these funds and provides prior approval for the proposed activities/costs for the respective year. The process for release of funds will be further detailed in the Program Terms and Conditions of Award.

B3. Anticipated Award Dates

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The anticipated award date is September 15, 2023.

B4. Period of Performance

The anticipated Period of Performance is 9/15/2023 – 9/14/2026.

- The anticipated Year 1 budget period is 9/15/2023 – 9/14/2024.
- The anticipated Year 2 budget period is 9/15/2024 – 9/14/2025.
- The anticipated Year 3 budget period is 9/15/2025 – 9/14/2026.

B5. Number of Awards

CMS will issue up to 3 awards maximum.

B6. Type of Award

The type of award issued under this NOFO is a grant.

B7. Type of Competition

Competitive:

Open to All Eligible Applicants that meet the Eligibility Requirements in Part C. A single institution may submit more than one application for consideration, provided that each application is scientifically distinct. An individual Principal Investigator (PI) must submit only one (1) application.

C. Eligibility Information

Applicants must meet the criteria selected in C1 as well as identify a Principal Investigator (PI) that meets the minimum requirements as described below:

1. Hold a Doctorate or Master's Degree in health services research, social sciences, epidemiology, medicine, law, or other related scientific/medical field.
2. Have a primary appointment (51% time or more) at a not-for-profit college, university, policy institute, foundation, think tank, or state/territory/tribal agency.
3. Demonstrate evidence of having designed and conducted research on health disparities and health equity, and reported the results for projects of similar size and scope as the applicant proposes for this effort.
4. Must have research aligned and described in A4. and be able to fund their ongoing research efforts.

- a. Must provide evidence of the availability and adequacy of the facilities, equipment, staffing, and financial management systems to conduct the project (analyze the data and submit 1 manuscript for publication) for the entire three years.
- b. Should an applicant be awarded funding, changes and staffing that affect this research must be reported. For example, reduction of staff or change in budget that would limit the ability to conduct research using HEDAP data.

C1. Eligible Applicants

Government Organizations

- State governments
- County governments
- City of Township governments
- Special District governments
- Native American tribal governments (Federally recognized)
- Native American tribal organizations (other than federally recognized tribal governments)

Education Organizations

- Independent School Districts
- Public and State Controlled Institutions of Higher Education
- Private institutions of higher education

Public Housing Organizations

- Public housing authorities
- Indian housing authorities

Nonprofit Organizations

- Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
- Nonprofits that do not have a 501(c)(3) status with the IRS, other than institutions of higher education
- For-profit Businesses** (organizations other than small businesses)
- Small Businesses**
- Individuals**
- Others**
- Unrestricted**

C2. Cost Sharing or Matching

No Cost Sharing or Matching required. All Applicants must be able to fund their research activities except for the access payment granted for CCW data to ResDAC.

C3. Letter of Intent

Applicants are highly encouraged, though not required, to submit an electronic, non-binding Letter of Intent (LOI) by July 16, 2023. Information from the LOI will assist CMS with planning for the application review process.

Prospective applicants are asked to submit a LOI that includes the following information:

- Descriptive title of proposed research
- Name(s), address(es), and telephone number(s) of the PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this Notice of Funding Opportunity

Letter of Intent should be sent to:

Centers for Medicare & Medicaid Services
Office of Minority Health
E-mail: HEResearch@cms.hhs.gov

C4. Ineligibility Criteria

N/A

C5. Single Application Requirement

More than one application per Higher Education Institution may be submitted with different Principal Investigators.

C6. Continued Eligibility

During the period of performance, award recipients must meet reporting and certification deadlines (as outlined in section F) to be eligible for continued funding throughout the 36-month budget and project period. In addition, award recipients must demonstrate satisfactory progress during the previous funding cycle(s) to ensure continued access to funding (as outlined in section A4. Program Requirements). At any time in the award cycle, recipients could receive decreased funding or their award could be terminated in accordance with 2 CFR 200.340 “Termination” if they fail to perform the requirements of the award. Funds from terminated awards will be used to make awards to other applicants capable of meeting satisfactory progress.

Continued funding is also contingent on compliance with the terms and conditions of award, the availability of funds.

Satisfactory progress (outlined in section A4 and F4) for selected award recipients includes, but is not limited to: publications; presentations; completion of Disparities Impact Statement; standardized data collection (disability questions per [2011 HHS data standards](#), language preference, gender identity, assigned sex at birth, sexual orientation, and appropriate questions

on social determinants of health [e.g. coverage type, transportation, social isolation, health literacy, housing insecurity, food insecurity, etc.]; analysis that includes demographic and SDOH data to conduct root cause analysis of disparities and results of solutions that were tested.

C7. EIN, UEI, Login.gov and SAM Regulations

All applicants must have the following to apply to grants.gov.:

- a valid Employer Identification Number (EIN), otherwise known as a Taxpayer Identification Number (TIN)
- a Unique Entity Identifier (UEI)
- a Login.gov account, and
- registration in the System for Award Management (SAM) database (<https://www.sam.gov/>) to be able to apply to grants.gov.

See Appendix II. Application and Submission Information for descriptions of EIN, UEI, and SAM.

C8. Faith-Based Organizations

Faith-Based Organizations are not eligible to apply.

C9. Other Eligibility Requirements

Only Institutions of Higher Education are eligible to apply.

D. Application and Submission Information

D1. Address to Request Application Package

Application materials are available at <https://www.grants.gov>. Please note that CMS requires electronic submission of applications for all Notice of Funding Opportunities through the Grants.gov website. Refer to Appendix II. Application and Submission Information for additional requirements and instructions.

D2. Content and Form of Application Submission

a. Application format

Applications determined to be ineligible, incomplete, and/or nonresponsive based on the initial screening may be eliminated from further review. However, in accordance with HHS Grants Policy, the CMS, Office of Acquisition and Grants Management (OAGM), Grants Management Officer in his/her sole discretion, may continue the review process for an ineligible application if it is in the best interests of the government to meet the objectives of the program.

Each application must include all contents of the application package, in the order indicated, and conform to the following formatting specifications:

- The required page size is 8.5” x 11” letter-size pages (one side only) with 1” margins (top, bottom, and sides). CMS does not accept other paper sizes.
- All pages of the project and budget narratives as well as other required narrative documents must be paginated in a single sequence.
- Font size must be at least 12-point with an average of 14 characters per inch (CPI).
- The Project Narrative must be double-spaced. The page limit for this document is 25 pages.
- The Business Assessment of Applicant Organization may be single spaced. The page limit for this document is 12 pages.
- Tables included within any portion of the application must have a font size of at least 12-point with a 14 CPI and may be single spaced. Tables are counted towards the applicable page limits.
- The project abstract is restricted to a one-page summary that may be single-spaced.
- The following required application documents are **excluded** from the page limitations described previously:
 - Standard Forms, Application Cover Letter/Cover Page (if applicable), copy of Letter of Intent, Project Site Location Form.
- The total number of additional appendices per application may be no more than 20.

b. Standard forms

The following forms must be completed with an electronic signature and enclosed as part of the application:

1. Project Abstract Summary

A one-page abstract serves as a succinct description of the proposed project and includes the goals of the project, the total budget, and a description of how the funds will be used. The abstract is often distributed to provide information to the public and Congress, so please write the abstract so that it is clear, accurate, concise, and without reference to other parts of the application. Exclude personal identifying information from the abstract. In the Grants Application Package at <https://www.grants.gov>, select the Project Abstract Summary and complete the form.

2. SF-424: Official Application for Federal Assistance

Note: On SF-424 “Application for Federal Assistance”

- On Item 15 “Descriptive Title of Applicant’s Project,” state the specific grant for which you are applying.
- Check “No” to item 19c, as Review by State Executive Order 12372 does not apply to this grant funding opportunity.
- The Authorized Organizational Representative (AOR) completes and signs this form.
Note: The signature of the individual that submits the application to Grants.gov populates throughout the application. The signature must match the name of the AOR. Other signatures will not be accepted.

The AOR is the designated representative of the applicant/Recipient organization with authority to act on the organization's behalf in matters related to the award and administration of grants. In signing a grant application, the AOR agrees that the organization will assume the obligations imposed by applicable Federal statutes and regulations and other terms and conditions of the award, including any assurances, if a grant is awarded. These responsibilities include accountability both for the appropriate use of funds awarded and the performance of the grant-supported project or activities as specified in the approved application.

1. SF-424A: Budget Information Non-Construction
2. SF-424B: Assurances-Non-Construction Programs
3. SF-LLL: Disclosure of Lobbying Activities

All applicants must submit this SF-LLL form. If your entity does not engage in lobbying, please insert "Non-Applicable" on the form and include the required AOR name, contact information, and signature. Please note that the application kit available online on the Grants.gov website is utilized for many programs and therefore Grants.gov may designate this form as optional to allow for flexibility amongst programs. However, this form is **required** as part of the application package and must be submitted for the application to be considered eligible for review.

4. Project Site Location Form(s)

All applicants must submit this Project Site Location form. Please note that the application kit available online in Grants.gov is utilized for many programs and therefore Grants.gov may designate this form as optional to allow for flexibility amongst programs. However, this form is **required** as part of the application package and must be submitted for the application to be considered eligible for review.

c. Application cover letter or cover page

The applicant may choose to include a cover letter or cover page to detail its interest in participation in HEDAP.

d. Program Requirements and Expectations

Project Narrative

Through the HEDAP, CMS provides funding to support three seats in the CMS VRDC in the CCW to allow researchers access to CMS restricted data for minority health research. Specifically, recipients will gain access to CMS data to conduct health services research focusing on, but not limited to, racial and ethnic minority groups; people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; individuals residing in rural areas; and individuals adversely affected by persistent poverty or inequality.

Applicants are required to provide a project narrative for specific applied research projects related to creative and innovative methods for using CMS data to identify, document, assess, and evaluate health disparities among Medicare, Medicaid and CHIP enrollees.

The Project Narrative must articulate in detail the proposed goals, measurable objectives, and milestones to be completed in accordance with the instructions and content requirements provided below and the specific criteria described in **F4. Reporting** and **E1. Criteria**. Please include the title “Project Narrative” at the beginning of the Project Narrative.

The 25-page project narrative shall provide a concise and complete description of the proposed project. It shall contain the information necessary for the review panelists to fully understand the project and cover all aspects of the project.

The Project Narrative should be written using the following format:

1. Relevance, feasibility, and potential impact
2. Methodology
3. Ability to implement the research project
4. Institutional structure, capabilities and budget support

1) Relevance, Feasibility, and Potential Impact

The application must demonstrate that the applicant has a thorough understanding of the specific health problem(s) within the population identified. The applicant should clearly describe the proposed project explaining what the researcher plans to do and why. This section of the application must describe the:

- Background, significance, review of literature, and need for the project
- Project purpose, goals, and objectives
- Relevance of the project to CMS’ mission/programs
- Feasibility – Does the applicant demonstrate knowledge of CMS data sufficient to ensure that the research question is appropriate and may be addressed in a sound, scientific manner using CMS data?
- Potential impacts - What insights will the project provide that may improve the overall health outcomes and quality of care, and/or reduce health disparities, for the targeted populations in Section A4?

2) Methodology

The applicant should explain how the research team intends to implement the project. The applicant should make a complete and concise presentation of the methodology that will be used. The application should provide clear and convincing evidence and supporting materials that reflect how the project is likely to improve quality of care and reduce health disparities for populations referenced in Section A4. Any innovative features of the proposed project should be highlighted. The application must include:

- Study design
- Hypotheses/research questions
- Data analysis plan

- Populations and setting
- Expected outcomes

3) Ability to Implement the Research Project

The applicant should provide detailed information to demonstrate their technical understanding and capability of performing the requirements of the project, including:

- A detailed implementation strategy and plan that includes a management plan describing tasks, responsible individuals, and timelines.
- The capabilities/responsibilities of all personnel and a description of how the personnel will be organized, to whom they will report, and their role in accomplishing the goals, objectives, and components of the project.

4) Institutional Structure, Capabilities, and Budget Support

The applicant should demonstrate clear and convincing evidence that the eligible entity has the organizational infrastructure and management capacity to conduct the research project effectively, including:

- Evidence of the availability and adequacy of the facilities, equipment, staffing, and financial management systems to conduct the project for the entire three years.
- Should an applicant be awarded funding, changes and staffing that affect this research should be reported. For example, reduction of staff or change in budget that would limit the ability to conduct research using HEDAP data.

e. Budget (SF-424A)

Fixed amount awards based on the cost of the support of a “seat” has been established based on a reasonable estimate of actual cost to access and obtain data from ResDAC. Award amounts are based on meeting specific requirements of this funding opportunity.

Applicants must use the budget category “Other” in Section B on the SF-424A. The three-year VRDC seat access award amount shall not exceed \$90,000 per award for a 36-month period.

Voluntary committed cost sharing or matching is not expected unless specifically stated otherwise in section C2.

For additional information and instructions for completing the SF-424A please refer to Appendix I. Guidance for Preparing

f. Business assessment of applicant organization (maximum 12 pages)

As required by 45 CFR §75.205 for competitive grants and cooperative agreements, CMS evaluates the risk posed by an applicant before they receive an award. This analysis of risk includes items such as financial stability, quality of management systems, internal controls and the ability to meet the management standards prescribed in 45 CFR Part 75.

An applicant must review, answer, and submit the business assessment questions outlined in Appendix III. Business Assessment of Applicant Organization.

g. Required Appendices (20-page limit)

- Key Staff Qualifications - Include resumes/curricula vitae of key personnel describing their qualifications. Resumes and/or curricula vitae should be a maximum of 5 pages each.
- Existing List of Research Projects and Roles.
- Letters of Agreement, Endorsement, or Support – An endorsement from the President or another equivalent official from your institution is required. Also required are endorsements from collaborating organizations outlining their contributions, roles, and responsibilities relative to the project and commitments that have been pledged for the proposed project. Include individual letters of support, as appropriate.
- Memoranda of Understanding/Agreements – Include documentation reflecting the collaborative relationships between relevant institutions.
- Institutional Review Board (IRB) Approval Plan – Describe plans to apply for IRB approval. Funding shall be contingent on obtaining IRB approval post-award.

Additional Supporting Documentation (10-page limit)

- Additional supporting documentation may be submitted; however, such materials shall be limited to information relevant to the specific scope and purpose of the proposed project.

D3. Unique Entity Identifier and System for Award Management (SAM)

Unless the applicant is an individual or Federal awarding agency that is excepted from those requirements under 2 CFR 25.110(b) or (c), or has an exception approved by the Federal awarding agency under 2 CFR 25.110(d)), each applicant is required to:

- i. register in SAM.gov before submitting its application;
- ii. provide a valid unique entity identifier in its application; and
- iii. continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency.

The Federal awarding agency may not make a Federal award to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements. If an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

D4. Submission Dates and Times

All applications must be submitted electronically and be received through <https://www.grants.gov> by the date and time set forth below. Applications received after 3:00 pm, Eastern Time, of the date set forth below will not be reviewed or considered for award.

Due Date for Applications: August 15, 2023, 3:00 pm Eastern Time (Baltimore, MD).

D5. Intergovernmental Review

Program is not subject to Executive Order 12372, “Intergovernmental Review of Federal Programs” (45 CFR 100). Please check box “C” on item 19 of the SF 424 (Application for Federal Assistance) as Executive Order 12372 does not apply to these grants.

D6. Cost Restrictions

Funding under this NOFO can only cover the cost of the payment for the access to the CMS CCW data under ResDAC for a three-year period. Funding cannot be used for any other purpose to include duplication or supplanting of other funding sources or to cover services provided after, or as a result of, the proposed approved research. Research must have its own budget for self-sustaining.

CMS prohibits funds under this award for any of the activities/costs outlined below unless an exception is specifically authorized by statute.

- To reimburse for pre-award costs.
- To match any other Federal funds.
- To provide services, equipment, or supports that are the legal responsibility of another party under Federal, State, or Tribal law (e.g., vocational rehabilitation or education services) or under any civil rights laws. Such legal responsibilities include, but are not limited to, modifications of a workplace or other reasonable accommodations that are a specific obligation of the employer or other party.
- To provide goods or services not allocable to the approved project.
- To supplant existing State, local, Tribal or private funding of infrastructure or services, such as staff salaries, etc.
- To be used by local entities to satisfy state matching requirements.
- To pay for construction.
- To pay for capital expenditures for improvements to land, buildings, or equipment which materially increase their value or useful life as a direct cost, except with the prior written approval of the Federal awarding agency.
- To pay for the cost of independent research and development, including their proportionate share of indirect costs (unallowable in accordance with 45 CFR 75.476).
- To expend funds 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.

D7. Mandatory Disclosure

Submission is required for all applicants, 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:

U.S. Department of Health and Human Services

Centers for Medicare and Medicaid Services
Office of Acquisition and Grants Management
Attn: Director, Division of Grants Management
7500 Security Blvd, Mail Stop B3-30-03
Baltimore, MD 21244-1850

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: MandatoryGranteeDisclosures@oig.hhs.gov

Materials should be scanned and emailed to the Grants Management Specialist assigned to this NOFO.

D8. HHS Form 690

Before CMS makes an award to a Recipient, the AOR must certify, by means of the signature on the application (SF-424), that the organization has on file with the HHS Office of Civil Rights (OCR) a one-time Assurance of Compliance with the statutes described in this subsection. The Assurance, Form HHS 690, is filed for the organization and is not required for each application. ([HHS 690 form \(PDF | 324 KB\)](#))

The HHS 690 form may be filed electronically via the U.S. Department of Health and Human Services’ Assurance of Compliance online portal at:

<https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf>

or be mailed to:

U.S. Department of Health & Human Services
Office for Civil Rights
200 Independence Ave., S.W. Room 509F
Washington, D.C. 20201

Subrecipients that receive funding from Recipients (including contractors under grants) rather than directly from CMS, also are required to file an HHS 690. The applicant/recipient is

responsible for determining whether those organizations have the required Assurance on file and, if not, ensuring that it is filed with OCR.

E. Application Review Information

E1. Criteria

Applications must be submitted in the required format, no later than the deadline. If an applicant does not submit all the required documents and does not address each of the topics described in D2. Content and Form of Application Submission Information (with cross reference to E1. Criteria), the applicant risks not being eligible and/or awarded. Applications are reviewed in accordance with criteria outlined below.

The total score for the application review criteria is 100 points.

All applicants must submit the following:

- Standard Forms;
- A Cover Letter, optional;
- A Project Narrative;
- Project Abstract
- Project Location Form
- Business Assessment of Applicant Organization; and
- Federally Negotiated Indirect Cost Rate Agreement (if applicable)

Section	Topics	Total Available Points	Scoring Criteria Breakdown
A.	Overall Impact	25	Considering all other application components in total, reviewers will provide an overall impact score assessment of the potential of the project to contribute to advancements in health equity for all populations as referenced in A4. How does the project clearly describe research that is relevant to CMS programs? (6 points) <ul style="list-style-type: none"> • How does the project propose to advance health care quality for racial and ethnic minorities; people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; individuals residing in rural areas; and/or individuals

			<p>adversely affected by persistent poverty or inequality? (7 points)</p> <ul style="list-style-type: none"> • How does the project align with Executive Order 13985 – Advancing Racial Equity and Support for Underserved Communities Through the Federal Government and Executive Order 14091 – Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government? (6 points) • How well does the proposed project address upstream drivers, social, and non-medical determinants of health? (6 points)
B.	Significance	25	<p>The applicant should address the following questions:</p> <ul style="list-style-type: none"> • How does the project address an important health equity related problem(s)? (6 points) • What is the scientific basis for your project? How does the project propose to address a health equity issue identified as a priority for CMS? (6 points) • What are the project goals? Do the goals integrate diversity and inclusion efforts with population health, patient care, quality, and safety? (6 points) • How will achieving the project’s aims improve knowledge, technical capability, workforce pipeline, or enhance quality, access, or outcomes for racial and ethnic minorities; people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; individuals residing in rural areas; and individuals adversely affected by persistent poverty or inequality? (7 points)

C.	Approach	15	<p>The applicant should address the following questions:</p> <ul style="list-style-type: none"> • What are the key research questions and aims, and how do the proposed methodologies and analysis address them? <ul style="list-style-type: none"> • How will the investigators ensure a robust and unbiased approach? (2.5 points) • What is the target population and setting, including the size of the target population, the proportion that is expected to be reached by the study, and rationale for this figure? (2.5 points) • What is the data collection and analysis plan? (2.5 points) <ul style="list-style-type: none"> CCW contains the following 100% Medicare files for years 1999 - 2020: <ul style="list-style-type: none"> ○ Fee-for-service institutional and non-institutional claims ○ Enrollment/eligibility ○ Assessment data ○ 100% Medicaid files for years 1999 – 2016 ○ 100% Part D Prescription Drug Event data for years 2006 - 2020 ○ Plan characteristics ○ Pharmacy characteristics ○ Prescriber characteristics ○ Formulary file - beginning with year 2010 ○ Other Research files – www.ccwdata.org • What challenges does the applicant anticipate and what potential mitigation strategies might the applicant pursue? (2.5 points) • How will the principal investigator of the award protect human subjects from research risks, particularly high risk and underserved populations, and what are the applicant’s plans to obtain IRB approval? (2.5 points)
D.	Innovation	15	<p>The applicant should address the following question:</p>

			<ul style="list-style-type: none"> How does the proposed project, improve or develop new policy or program ideas that advance equity for all racial and ethnic minorities; people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; individuals residing in rural areas; and individuals adversely affected by persistent poverty or inequality? (15 points)
E.	Investigator(s)	10	<p>The applicant should address the following questions:</p> <ul style="list-style-type: none"> What skills does the PI have to support a heightened level of success on the proposed project? (2.5 points) What are staff members' capabilities and how is their training, experience, and/or ongoing record of accomplishment well suited to the project? (2.5 points) How will staff be organized, and what will be their responsibilities and roles? (2.5 points) If the project has multiple principal investigators, how will these investigators integrate their expertise and approach joint leadership of the project? (2.5 points) <p>Applicants should include resumes or curricula vitae of key staff members describing their qualifications as an appendix. Resumes/curricula vitae should be a maximum of 5 pages each.</p>
F.	Environment	10	<p>The applicant should address the following questions:</p> <ul style="list-style-type: none"> How will the applicant's institutional infrastructure, organizational resources, and management capacity enable project success? Applicants should describe the availability and adequacy of the facilities, equipment, and financial management systems needed to conduct the project. (2.5 points)

		<ul style="list-style-type: none"> • What are the unique aspects of the applicant’s institution that will enable the project’s success? (2.5 points) • What is the applicant’s plan for budget and performance monitoring (e.g., how does the PI plan to monitor the proposed budget and progress of the proposed research)? (2.5 points) • What are the collaborative relationships supporting the proposed research project that have been established or that may be established between the applicant and other organizations? Are roles and responsibilities well defined? (2.5 points) <p>The evaluation shall consider whether the applicant possesses the organizational infrastructure and management capacity to conduct the research project, as well as a comprehensive budget reflecting all costs of staffing for implementing the health services research activities.</p> <p>Letters of support from collaborating organizations outlining their tentative contributions, roles, and responsibilities relative to the research project should be included in the appendix.</p>
Total Available Points: 100		

E2. Merit Review and Selection Process

This is an anticipated federal review conducted by CMS employees.

Awards may be adjusted to a lower amount if the applicant fails to meet performance milestones (refer to section F5. Reporting).

The application itself is not a legally binding agreement and does not require any applicant or CMS to enter into a legal agreement. CMS will select recipients at CMS’s sole discretion unless statutorily prohibited. Such selection will not be subject to administrative or judicial review, per Section 1115A(d)(2)(B) of the Act.

Please refer to Appendix V. Review and Selection Process for more information on the review and selection process.

E3. Federal Awardee Performance Integrity Information System (FAPIS)

In accordance with 45 CFR Part 75:

- i. CMS, prior to making a Federal award with a total amount of Federal share greater than the simplified acquisition threshold¹, is required to review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently FAPIS) (see 41 U.S.C. 2313);
- ii. An applicant, at its option, may review information in the designated integrity and performance systems accessible through SAM and comment on any information about itself that the HHS awarding agency previously entered and is currently in the designated integrity and performance system accessible through SAM.
- iii. CMS will consider any comments by the applicant, in addition to the other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicant as described in §75.205.

F. Federal Award Administration Information

F1. Federal Award Notices

If successful, applicants will receive a Notice of Award (NoA) signed and dated by the CMS Grants Management Officer. The NoA is the legal document authorizing the grant award and issued to the applicant as listed on the SF-424. The NoA is available to the applicant organization through the online grants management system used by CMS and recipient organizations, GrantSolutions. Any communication between CMS and applicant prior to issuance of the NoA is not an authorization to begin performance of a project.

If unsuccessful, CMS notifies the applicant electronically to the email address as listed on its SF-424, within 30 days of the award date of the program.

F2. Administrative and National Policy Requirements

A. National/Public Policy Requirements

By signing the application, the authorized organizational official certifies that the organization will comply with applicable public policies. Each recipient is responsible for establishing and maintaining the necessary processes to monitor its compliance and that of its employees and, as appropriate, subrecipients and contractors under the award with these requirements. Recipients should consult the applicable Appropriations Law, Exhibit 3 of the HHS Grants Policy Statement, titled Public Policy Requirements, located in Section II, pages 3-6, as well as the

¹ *Simplified acquisition threshold* means the dollar amount below which a non-Federal entity may purchase property or services using small purchase methods. Non-Federal entities adopt small purchase procedures to expedite the purchase of items costing less than the simplified acquisition threshold. The simplified acquisition threshold is set by the Federal Acquisition Regulation at 48 CFR Subpart 2.1 (Definitions) and in accordance with 41 U.S.C. 1908.

terms and conditions of award for information on potentially applicable public policy requirements.

Recipients should review and comply with the reporting and review activities regarding accessibility requests outlined in Appendix IV, Accessibility Provisions to this Notice of Funding Opportunity.

B. Administrative Requirements

- All equipment, staff, and other budgeted resources and expenses must be used exclusively for the projects identified in the applicant's original application or agreed upon subsequently with CMS, and may not be used for any prohibited uses.
- Consumers and other stakeholders must have meaningful input into the planning, implementation, and evaluation of the project.
- This award is subject to 45 CFR Part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS awards [available at <http://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75>], which implements 2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards ("Uniform Guidance") effective December 26, 2014. See below for more information.

Uniform Administrative Requirements, Cost Principles, and Audit Requirements

Applicant and recipients should take note of the following information found in 45 CFR Part 75:

Uniform Administrative Requirements

In accordance with 45 CFR §75.112, all award recipients receiving federal funding from CMS must establish and comply with the **conflict of interest policy requirements** outlined by CMS (see Appendix VI).

In accordance with 45 CFR §75.113, **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. Non-Federal entities that have received a Federal award including the term and condition outlined in Appendix XII to 45 CFR Part 75 are required to report certain civil, criminal, or administrative proceedings to SAM. Failure to make the required disclosures can result in the imposition of any of the remedies described in §75.371, including suspension or debarment. (See also 2 CFR Parts 180 and 376, and 31 U.S.C. 3321). For specific information on reporting such disclosures to CMS and HHS please see Section F3. Terms and Conditions of this NOFO.

Audit Requirements

The audit requirements in 45 CFR Part 75, Subpart F, apply to each award recipient fiscal year that begins on or after December 26, 2014. A non-Federal entity that expends \$750,000 or more in Federal awards during the non-Federal entity's fiscal year must have a single or program-

specific audit conducted for that year in accordance with the provisions of Subpart F, Audit Requirements.

Commercial Organizations (including for-profit hospitals) have two options regarding audits, as outlined in 45 CFR §75.501 (see also 45 CFR §75.216).

F3. Terms and Conditions

This Notice of Funding Opportunity is subject to the Department of Health and Human Services

Grants Policy Statement (HHS GPS)

at <http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary. Standard and program specific terms of award will accompany the NoA. Potential applicants should be aware that special requirements could apply to cooperative agreement awards based on the circumstances of the effort to be supported and/or deficiencies identified in the application by the HHS review panel.

HHS regulation (45 CFR Part 75) supersedes information on administrative requirements, cost principles, and audit requirements for grants and cooperative agreements included in the current HHS Grants Policy Statement where differences are identified. Recipients must also agree to respond to requests that are necessary for the evaluation of national efforts and provide data on key elements of their own grant or cooperative agreement activities.

Non-Discrimination Legal Requirements for Recipients of Federal Financial Assistance

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which you agree, as a condition of receiving the grant, to administer your programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. **See Section D8 for additional information regarding HHS 690.** This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination based on sexual orientation, and gender identity, The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

- For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov/>.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.

- HHS funded health and education programs must be administered in an environment free of sexual harassment, see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html> .
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html> .

Material Noncompliance

CMS may terminate any award for material noncompliance. Material noncompliance includes, but is not limited to, violation of the terms and conditions of the award; failure to perform award activities in a satisfactory manner; improper management or use of award funds; or fraud, waste, abuse, mismanagement, or criminal activity.

Bankruptcy. In the event a recipient or one of its subrecipients enters proceedings relating to bankruptcy, whether voluntary or involuntary, the Recipient agrees to provide written notice of the bankruptcy to CMS. The recipient must furnish the written notice within five (5) days of the initiation of the proceedings relating to bankruptcy filing and sent to the CMS Grants Management Specialist and Project Officer. This notice includes:

- the date on which the bankruptcy petition was filed,
- the identity of the court in which the bankruptcy petition was filed,
- a copy of all the legal pleadings, and
- a listing of Government grant and cooperative agreement numbers and grant offices for all, and
- Government grants and cooperative agreements against which final payment has not been made.

Intellectual Property

Recipients under this funding opportunity must comply with the provisions of 45 CFR § 75.322, Intangible property and copyrights. The non-Federal entity may copyright any work that is subject to copyright and was developed, or for which ownership was acquired, under a Federal award. The Federal awarding agency reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so. The non-Federal entity is subject to applicable regulations governing patents and inventions, including government-wide regulations issued by the Department of Commerce at 37 CFR part 401.

The Federal Government has the right to:

- (1) Obtain, reproduce, publish, or otherwise use the data produced under a Federal award; and
- (2) Authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

Prohibition on certain telecommunications and video surveillance services or equipment:

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 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.

F4. Reporting

Integrity and Performance Reporting. The Notice of Award (NoA) will contain a provision for integrity and performance reporting in FAPIIS, as required in 45 CFR part 75 Appendix XII.

a. Progress Reports

Recipients must agree to cooperate and comply with any Federal oversight as it may pertain to the award. Recipients must provide, annual, and final reports, as required, in the form prescribed by the Department of Health and Human Services, as well as any additional reports as required.

CMS requires the following milestones as a condition of award:

Annual Reporting Periods	Milestones	Due Dates
1	Obtain Institutional Review Board approval	Within 3 months of award issue date.

1	Advise CMS of the status of the Data Use Agreement (DUA) applications to ResDAC	Within 3 months of award issue date.
1	Submit a Disparities Impact Statement	Within 3 months of award issue date.
1	Submit DUA application to ResDAC	Within 6 months of award issue date.
1	Report to CMS a “good status ready to have DUA approval” by ResDAC or “DUA in process” by ResDAC, and confirm there are no issues with staffing or funding.	Within 9 months of award issue date.
1,2,3	Commit to meeting twice a year (via conference call) with CMS/OMH	Dates to TBD
3	Complete Project	9/14/2026
3	Submit at least one manuscript to a peer-reviewed healthcare, medical, and/or public health journal describing the findings of the study. All publications must be reviewed by CMS prior to submission as detailed in the Notice of Award Terms and Conditions.	No later than 3 months prior to project end date.

Semi-annual programmatic progress reports shall be due every 6 months of the project period. CMS will provide recipients further information on the requirements of the programmatic progress reports.

Investigators must submit a complete draft of the final progress report no later than 60 days after the end of the project period. Investigators must address all feedback from the project officer and submit a finalized version of their final progress report 120 days after the end of the project period.

The absence of a satisfactory project status (see section A4) may result in CMS deciding to terminate the HEDAP recipient Notice of Award, and to allocate those funds to other projects capable of performing by CMS standards.

The awardee shall submit reports electronically to GrantSolutions. The program progress narrative report elements are as follows:

1. Program Name;
2. Principle Investigator Name;
3. Reporting Period;
4. Budget Status – Include amounts for planned expenditure, actual expenditure, and deficit/surplus;
5. Project description – Short summary;

6. Milestones – Milestones are high-level goals that often define the phases of a project. Record here milestones that have been reached at this point in the project;
7. Accomplishments – Tasks that were accomplished during this reporting period;
8. Projected Goals – Goals projected to be completed during the next reporting period; and
9. Issues – Emerging financial, research-related, staffing, or other challenges or obstacles that must be addressed for the project to be successful; once an issue is noted in a report, its progress should be tracked and documented in all subsequent reports until resolved.

All report submissions must be 508 compliant. For more information on ensuring 508 compliance: <https://www.hhs.gov/web/section-508/index.html>. More details of the required semi-annual and final report will be outlined in the NoA and terms and conditions of award.

b. Financial Reports

CMS recipients are required to record recipient expenses in real-time as well as submit semi-annual or annual expenditure FFRs as described below.

Semi-Annual, Annual, and Final Expenditure Reporting

Recipient must also report on Federal expenditures, Recipient Share (if applicable), and Program Income (if applicable and/or allowable) at least annually via the Payment Management System. Frequency of required expenditure reporting, whether semi-annually or annually, is stipulated in the Program Terms and Conditions of award. Expenditures, Recipient Share, and Program Income is reflected through completion of lines 10.d through 10.o of the FFR.

c. Federal Funding Accountability and Transparency Act Reporting Requirements

New awards issued under this NOFO are subject to the reporting requirements of the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109– 282), as amended by section 6202 of Public Law 110–252 and implemented by 2 CFR Part 170. Grant and cooperative agreement recipients must report information for each first-tier sub- award of \$30,000 or more in Federal funds and executive total compensation for the recipient’s and sub-recipient’s five most highly compensated executives as outlined in Appendix A to 2 CFR Part 170 (available online at <https://www.fdrs.gov/>).

d. Audit Requirements

Recipients must comply with audit requirements outlined in HHS regulation 45 CFR Part 75 (implementing 2 CFR Part 200). See Subpart F – Audit Requirements. <http://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75#sp45.1.75.f>.

e. Payment Management System Reporting Requirements

Once CMS issues an award, the funds are posted in recipient accounts established in the Payment Management System (PMS). Recipients may then access their funds by using the PMS funds request process.

The PMS funds request process enables recipients to request funds using a Personal Computer with an Internet connection. The funds are delivered to the recipient via Electronic Funds

Transfer (EFT). If you are a new recipient, please go to PMS Access Procedures to find information to register in PMS. If you need further help with that process, please contact the One-DHHS Help Desk via email at pmssupport@psc.gov or call (877) 614-5533 for assistance.

f. Government-wide Suspension and Debarment Reporting Requirements

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification;

- 1) You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. § 3354).
- 3) If you are unable to attest to the statements in this certification, you must include an explanation and insert in “Other Relevant Documents”.

G. CMS Contacts

G1. Programmatic Questions

For Programmatic questions about this funding opportunity, please contact:

Centers for Medicare & Medicaid Services Office of Minority Health
HEResearch@cms.hhs.gov

G2. Administrative/Budget Questions

For administrative or budget questions about this funding opportunity, please contact:

HEResearch@cms.hhs.gov

H. Other Information

CMS is not obligated to make any Federal award because of the publication of this NOFO.

Publication of this NOFO does not oblige CMS to award any specific project or to obligate any available funds.

CMS may cancel or withdraw this NOFO at any time.

Award decisions are discretionary and are not subject to appeal to any CMS or HHS official or board.

Appendix I. Guidance for Preparing a Budget Request and Narrative

Applicants must request funding only for activities that will support this specific Notice of Funding Opportunity. All applicants must submit the Standard Form SF-424A. The Standard Form SF-424A must include costs for the entire 36-month period of performance. Please review the directions below to ensure both documents are accurately completed and consistent with application requirements.

Standard Form SF-424A

All applicants must submit an SF-424A. To fill out the budget information requested on form SF-424A, review the general instructions provided for form SF-424A and comply with the instructions outlined below.

- Note: The directions in the Notice of Funding Opportunity (NOFO) may differ from those provided by Grants.gov. Please follow the instructions included in this NOFO as outlined below when completing the SF-424A.
- Note: The total requested on the SF-424 (Application for Federal Assistance) reflects the overall total requested on the SF-424A (Budget Information – Non-Construction) for the entire period of performance.

Section A – Budget Summary

- *Grant Program Function or Activity* (column a) = Enter “Name of Notice of Funding Opportunity” in row 1.
- *New or Revised Budget, Federal* (column e) = Enter the Total Federal Budget Requested for the project period in rows 1 and 5.
- *New or Revised Budget, Non-Federal* (column f) = Enter Total Amount of any Non-Federal Funds Contributed (if applicable) in rows 1 and 5. Voluntary committed cost sharing or matching is not expected unless specifically stated otherwise in section C2.
- *New or Revised Budget, Total* (column g) = Enter Total Budget Proposed in rows 1 and 5, reflecting the sum of the amount for the Federal and Non-Federal Totals.

Section B – Budget Categories

- Enter the total costs requested (\$30,000 per year for three years) into the “Other” Class Category (Section B, number 6, category h) for each year of the period of performance.
- Column (1) = Enter Year 1 costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 1 line items is entered in column 1, row k (sum of row i and j).
- Column (2) = Enter Year 2 estimated costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 2 line items is entered in column 2, row k (sum of row i and j).
- Column (3) = (If applicable) Enter Year 3 estimated costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 3-line items are entered in column 3, row k (sum of row i and j).

- Column (4) = (If applicable) Enter Year 4 estimated costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 4 items are entered in column 4, row k (sum of row i and j).
- Column (5) = Enter total costs for the period of performance for each line item (rows a-h), direct total costs (row i), and indirect costs (row j). The total costs for all line items are entered in row k (sum of row i and j). The total in column 5, row k should match the total provided in Section A – Budget Summary, New or Revised Budget, column g, row 5.

Appendix II. Application and Submission Information

Please CTRL/Click to access links or paste to your browser. Please note these are the most up-to-date directions and links we have. Applicants are advised to check the websites for any changes. Also, phone numbers are provided if additional assistance is needed as several websites have made recent changes to links and directions.

This NOFO contains all the instructions to enable a potential applicant to apply. The application is written primarily as a narrative with the addition of standard forms required by the Federal government for all grants and cooperative agreements.

EIN, UEI, LOGIN.GOV AND SAM REQUIREMENTS (ALL APPLICATIONS)

Employer Identification Number

All applicants under this Notice of Funding Opportunity must have an Employer Identification Number (EIN), otherwise known as a Taxpayer Identification Number (TIN), to apply. **Please note, applicants should begin the process of obtaining an EIN/TIN as soon as possible after the Notice of Funding Opportunity is posted to ensure this information is received in advance of application deadlines. The process to obtain an EIN typically takes up to 5 weeks.**

Unique Entity Identifier (UEI)

Applicants must have a UEI number to apply.

Applicants should obtain a Unique Entity Identifier (UEI) number as soon as possible after the Notice of Funding Opportunity is posted to ensure all registration steps are completed in time.

See the following links for additional information on obtaining a UEI:

- GAO: <https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/iae-systems-information-kit/unique-entity-identifier-update>
- Grants.gov: <https://www.grants.gov/web/grants/forms/planned-uei-updates.html>

Login.gov

Users must sign in to Grants.gov with Login.gov credentials.

<https://grantsgovprod.wordpress.com/2022/05/04/how-to-create-a-grants-gov-account-and-link-to-a-login-gov-account/>

System for Award Management (SAM)

The applicant must register in the System for Award Management (SAM) database to be able to submit the application. Applicants can access <https://www.sam.gov/> and complete the online registration. UEI and EIN/TIN numbers are required to complete the registration process. To register one or more domestic entities and appoint an entity administrator, the applicant organization must send a notarized letter to SAM.

Applicants should begin the SAM registration process as soon as possible after the Notice of Funding Opportunity is posted to ensure that it does not impair your ability to meet required submission deadlines. The process to register in SAM typically takes up to 2 weeks following receipt of the notarized letter (additional 5 weeks if an EIN must be established first).

Each year organizations and entities registered to apply for Federal grants or cooperative agreements through Grants.gov (or GrantSolutions as applicable) must renew their registration with SAM. **Failure to renew SAM registration prior to application submission will prevent an applicant from successfully applying via Grants.gov (or GrantSolutions as applicable). Similarly, failure to maintain an active SAM registration during the application review process can prevent CMS from issuing your agency an award.**

Applicants must also successfully register with SAM prior to registering in the Federal Funding Accountability and Transparency Act Subaward Reporting System (FSRS) as a prime awardee user. Please also refer to F5.c (Federal Funding Accountability and Transparency Act Reporting Requirements) of this Funding Opportunity for more information. Primary awardees must maintain a current registration with the SAM database, and **may make subawards only to entities that have UEI numbers.**

Organizations must report executive compensation as part of the registration profile at <https://www.sam.gov/> by the end of the month following the month in which this award is made, and annually thereafter (based on the reporting requirements of the Federal Funding Accountability and Transparency Act (FFATA) of 2006 (Pub. L. 109-282), as amended by Section 6202 of Public Law 110-252 and implemented by 2 CFR Part 170).

How to Apply to CMS through Grants.gov

CMS requires applications for all competitive Notice of Funding Opportunities to be submitted electronically through <http://www.grants.gov/>. For assistance with this process contact <https://www.grants.gov/web/grants/support.html> or 1-800-518-4726. Below is an overview of the instructions from the Grants.gov website. Applicants can access the site directly for more detailed information.

First Steps:

- *Obtain A UEI number.*
- *Complete SAM.gov registration*
- *Create a Login.gov Account (Users must sign in to Grants.gov with Login.gov credentials)*
<https://grantsgovprod.wordpress.com/2022/05/04/how-to-create-a-grants-gov-account-and-link-to-a-login-gov-account/#CreateALoginGovAccount>
- *Register.* Click the Register link and complete the on-screen instructions or refer to detailed instructions here:
<https://www.grants.gov/web/grants/applicants/registration.html>.
- *To link your Grants.gov account to a Login.gov account.* See detailed instructions here:

<https://grantsgovprod.wordpress.com/2022/05/04/how-to-create-a-grants-gov-account-and-link-to-a-login-gov->

- *Add a Profile to the Account:* The profile corresponds to a single applicant organization the user represents (i.e., an applicant) or an individual applicant. If you work for or consult with multiple organizations and have a profile for each, you may log in to one Grants.gov account to access all your grant applications. To add an organizational profile, enter the UEI (Unique Entity Identifier) for the organization in the field while adding a profile. For more detailed instructions about creating a profile refer to: <https://www.grants.gov/web/grants/applicants/registration/add-profile.html>
- **NOTE: EBiz POC Authorized Profile Roles:** EBiz POCs will no longer use their UEI or DUNS Number during login. EBiz POCs will use an applicant account associated with their email address and UEI (Unique Entity Identifier) by using an existing applicant account or **registering a new one**. Beginning January 21, 2023, any applicant user whose Grants.gov account and profile is associated with the same email address and UEI as the EBiz POC registered in SAM.gov will be recognized as the EBiz POC in Grants.gov. If the EBiz POC email address in SAM.gov changes, the user will no longer be recognized as the EBiz POC in Grants.gov. However, this user will retain the Expanded AOR role until it is removed by another Expanded AOR. <https://grantsgovprod.wordpress.com/2022/12/14/improvements-to-ebiz-account-management/>
- *Track Role Status:* To track your role request, refer to: <https://www.grants.gov/web/grants/applicants/registration/track-role-status.html>
- *Electronic Signature:* When applications are submitted through Grants.gov, the name of the organization applicant with the AOR role that submitted the application is inserted into the signature line of the application, serving as the electronic signature. The EBiz POC **must** authorize people who are able to make legally binding commitments on behalf of the organization as a user with the AOR role; **this step is often missed and it is crucial for valid and timely submissions.**

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 Notice of Funding Opportunity (alternatively, may be referred to as Funding Opportunity Announcement (FOA)), you can create individual instances of a workspace. *Note:* Search for the application package in by entering the Federal Assistance Listings (CFDA) number. This number is shown on the Federal Assistance Listings (or CFDA) website at <https://sam.gov> and cover page of the funding opportunity.

Applications cannot be accepted through any email address. Full applications can only be accepted through <https://www.grants.gov>. Full applications cannot be received via paper mail, courier, or delivery service.

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

<https://www.grants.gov/web/grants/applicants/workspace-overview.html>

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

2) *Complete a Workspace*: Add participants to the workspace to work on the application together, complete all the required forms online or by downloading PDF versions, and check for errors before submission. The Workspace progress bar will display the state of your application process as you apply. As you apply using Workspace, you may click the blue question mark icon near the upper-right corner of each page to access context-sensitive help.

a. *Adobe Reader*: If you decide not to apply by filling out webforms you can download individual PDF forms in Workspace. The individual PDF forms can be downloaded and saved to your local device storage, network drive(s), or external drives, then accessed through Adobe Reader.

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

<https://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html>

b. *Mandatory Fields in Forms*: In the forms, you will note fields marked with an asterisk and a different background color. These fields are mandatory fields that must be completed 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. Once it is completed, the information will transfer to the other forms.

3) *Submit a Workspace*: An application may be submitted through workspace by clicking the Sign and Submit button on the Manage Workspace page, under the Forms tab.

Grants.gov recommends submitting your application package at least 24-48 hours prior to the close date to provide you with time to correct any potential technical issues that may disrupt the application submission.

4) *Track a Workspace Submission*: After successfully submitting a workspace application, a Grants.gov Tracking Number (GRANTXXXXXXXX) is automatically assigned to the application. The number will be listed on the Confirmation page that is generated after submission. Using the tracking number, access the Track My Application page under the Applicants tab or the Details tab in the submitted workspace.

For additional training resources, including video tutorials, refer to:

<https://www.grants.gov/web/grants/applicants/applicant-training.html>

Applicant Support: 24/7 support is available via the toll-free number 1-800-518-4726 and email at <https://www.grants.gov/web/grants/support.html> . For questions related to the specific grant opportunity, contact the number listed in the application package of the grant 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 CMS with tracking your issue and understanding background information on the issue.

Timely Receipt Requirements and Proof of Timely Submission

All grant and cooperative agreement applications must be submitted electronically and **received** through <https://www.grants.gov> by 3:00 p.m. Eastern Standard or Daylight Time (Baltimore, MD) by the applicable deadline date. Please refer to the Executive Summary of this Notice of Funding Opportunity for submission deadline date.

Proof of timely submission is automatically recorded and an electronic date/time stamp is generated within the system when the application is successfully received by Grants.gov. The applicant with the AOR role who submitted the application will receive an acknowledgement of receipt and a tracking number (GRANTXXXXXXXX) with the successful transmission of their application. This applicant with the AOR role will also receive the official date/time stamp and Grants.gov Tracking number in an email serving as proof of their timely submission.

Please note, applicants may incur a time delay before they receive acknowledgement that the application has been accepted by the Grants.gov system. Applicants should not wait until the application deadline to apply because notification by Grants.gov that the application is incomplete may not be received until close to or after the application deadline, eliminating the opportunity to correct errors and resubmit the application. Applications submitted after the deadline, because of errors on the part of the applicant, will not be reviewed.

When CMS successfully retrieves the application, 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 who submitted the application. Again, proof of timely submission shall be the official date and time that Grants.gov receives your application. Applications received after the established due date for the program will be considered late and will not be considered for funding by CMS.

Applicants using slow internet, such as dial-up connections, should be aware that transmission can take some time before your application is received. 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 attempting to submit the application. The 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. To be considered timely, applications must be received by the published deadline date. However, a general extension of a published application deadline that affects all State applicants or only those in a defined geographical area may be authorized by circumstances that affect the public at large, such as natural disasters (e.g., floods or hurricanes) or disruptions of electronic (e.g., application receipt services) or other services, such as a prolonged blackout. This statement does not apply to an individual entity having internet service problems. For there to be any consideration there must be an effect on the public at large.

Grants.gov complies with Section 508 of the Rehabilitation Act of 1973. If an individual uses assistive technology and is unable to access any material on the site, including forms contained within an application package, the individual can e-mail the contact center at <https://www.grants.gov/web/grants/support.html> for help, or call 1-800-518-4726.

Appendix III. Business Assessment of Applicant Organization

Applicants review and answer the business assessment questions outlined below. There are eleven (11) topic areas labeled A-K, with a varying number of questions within each topic area. **Applicants MUST provide a brief substantive answer to each question (and supporting documentation as applicable).** If the answer to any question is non-applicable, please provide an explanation. Please note, if CMS cannot complete its review without contacting the applicant for additional clarification, the applicant risks selection for award.

A. General Information

1. Provide organization:
 - a. Legal name:
 - b. EIN (include PMS prefix and suffix, if applicable-ex. **1-12356789-A1**):
 - c. Organizational Type:
2. What percentage of the organization's capital is from Federal funding? (percentage = total Federal funding received in previous fiscal year / organization's total gross revenue in previous fiscal year).
3. Does/did the organization receive additional oversight (ex: Correction Action Plan, Federal Awardee Performance and Integrity Information System (FAPIIS) finding, reimbursement payments for enforcement actions) from a Federal agency within the past 3 years due to past performance or other programmatic or financial concerns with the organization)?
 - a. If yes, please provide the following information: Name of the Federal agency; reason for the additional oversight as explained by the Federal agency
 - b. If resolved, please indicate how the issue was resolved with the agency.
4. Does the organization currently manage grants with other U.S. Department of Health and Human Services components or other Federal agencies?
5. Explain your organization's process to ensure annual renewal in System for Award Management (to include FAPIIS).
6. Explain your organization's process to comply with (a) [45 CFR 75.113](#) Mandatory Disclosures and (b) your organization's process to comply with FFATA requirements.
7. Do you have conflict of interest policies? Does your organization or any of its employees have any personal or organizational conflicts of interest related to the possible receipt of these CMS award funds? If yes, please explain and provide a mitigation plan.
8. Does your organization currently, or in the past, had delinquent Federal debt in the last 3 years? If yes, please explain.
9. Has the organization obtained fidelity bond insurance coverage for responsible officials and employees of the organization in amounts required by statute or organization policy? What is that amount?
10. Do you have (and briefly describe) policies and procedures in place to meet the requirements below? If not, explain your plan and estimated timeline for establishing these policies and procedures if selected for award.

- a. make determinations between subrecipients versus contracts in accordance with [45 CFR 75.351](#)?
- b. notify entities at the time of the award/agreement if they are a subrecipient in compliance with [45 CFR 75.352](#)?
- c. manage, assess risk, review audits, and monitor the subrecipients as necessary to ensure that subawards are used for authorized purposes in compliance with laws, regulations, and terms and conditions of the award and that established subaward performance goals are achieved (45 CFR § [75.351–75.353](#))?

B. Accounting System

1. Does the organization have updated (last two years) written accounting policies and procedures to manage federal awards in accordance with 45 CFR Part 75?
 - a. If no, please provide a brief explanation of why not.
 - b. Describe the management of federal funds and how funds are separated (not co-mingling) from other organizational funds.
2. Briefly describe budgetary controls in effect to preclude incurring obligations more than:
 - a. Total funds available for an award.
 - b. Total funds available for a budget cost category.
3. Has any government agency rendered an official written opinion within the last 3 years concerning the adequacy of the organization’s accounting system for the collection, identification, and allocation of costs under Federal awards?
 - a. If yes, please provide the name and address of the Agency that performed the review.
 - b. Provide a summary of the opinion.
 - c. How did your organization resolve any concerns?
4. How does the accounting system provide for recording the non-Federal share and in-kind contributions (if applicable for a grant program)?
5. Does the organization's accounting system provide identification for award funding by federal agency, pass-through entity, Assistance Listing (CFDA), award number and period of funding? If yes, how does your organization identify awards? If not, please explain why not.

C. Budgetary Controls

1. What are the organization’s controls utilized to ensure that the Authorized Organizational Representative (AOR), as identified on the SF-424, approves all budget changes for the federal award?
2. Describe the organization’s procedures for minimizing the time between transfer of funds from the U.S. Treasury (e.g. Payment Management System) and disbursement for grant activities (See 45 CFR §75.305, “Payment.”).

D. Personnel

1. Does the organization have a current organizational chart or similar document establishing clear lines of responsibility and authority?
 - a. If yes, please provide a copy.
 - b. If no, how are lines of responsibility and authority determined?

2. Does the organization have updated (last two years) written Personnel and/or Human Resource policies and procedures? If no, provide a brief explanation.
3. Does the organization pay compensation to Board Members?
4. Are staff responsible for fiscal and administrative oversight of HHS awards (Grants Manager, CEO, Financial Officer) familiar with federal rules and regulations applicable to grants and cooperative agreements (e.g. [45 CFR Part 75](#))?
5. Please describe how the payroll distribution system accounts for, tracks, and verifies the total effort (100%) to determine employee compensation.

E. Payroll

1. In preparation of payroll is there a segregation of duties for the staff who prepare the payroll and those that sign the checks, have custody of cash funds and maintain accounting records? Please describe.

F. Consultants (See appendix I in the NOFO for relevant information)

1. Are there written policies or consistently followed procedures regarding the use of consultants which detail the following (include explanation for each question below)?
 - a. Briefly describe the organization’s method or policy for ensuring consultant costs and fees are allowable, allocable, necessary and reasonable.
 - b. Briefly describe the organization’s method or policy to ensure prospective consultants prohibited from receiving Federal funds are not selected.

G. Property Management

1. Briefly describe the system for property management (tangible or intangible) utilized for maintaining property records consistent with 45 CFR 75.320(d). **Refer to ([45 CFR 75.2](#)) for definitions of property to include personal property, equipment, and supplies.
2. Does the organization have adequate insurance to protect the Federal interest in equipment and real property (see [45 CFR §75.317](#), “[Insurance coverage](#).”)? How does the organization calculate the amount of insurance?

H. Procurement

Describe the organization’s procurement procedures (in accordance with [45 CFR §75.326--§75.335](#), “Procurement procedures”)? If there are no procurement procedures, briefly describe how your organization handles purchasing activities. A. Include individuals responsible and their roles. B. Describe the competitive bid process for procurement purchases of equipment, rentals, or service agreements that are over certain dollar amounts.

I. Travel

1. Describe the organizations written travel policy. Ensure, at minimum, that:
 - a. Travel charges are reimbursed based on actual costs incurred or by use of per diem and/or mileage rates (see [45 CFR §75.474](#), “Travel costs.”).
 - b. Receipts for lodging and meals are required when reimbursement is based

- on actual cost incurred.
- c. Subsistence and lodging rates are equal to or less than current Federal per diem and mileage rates.
- d. Commercial transportation costs incurred at coach fares unless adequately justified. Lodging costs do not exceed GSA rate unless adequately justified (e.g. conference hotel).
- e. Travel expense reports show purpose and date of trip.
- f. Travel costs are approved by organizational official(s) and funding agency prior to travel.

J. Internal Controls

1. Provide a brief description of the applicant’s internal controls that will provide reasonable assurance that the organization will manage award funds properly. (see [45 CFR §75.303](#), “Internal controls.”)
2. What is your organization’s policy on separation of duties as well as responsibility for receipt, payment, and recording of cash transactions?
3. Does the organization have internal audit or legal staff? If not, how do you ensure compliance with the award? Please describe.
 4. If the organization has a petty cash fund how is it monitored?
5. Who in the organization reconciles bank accounts? Is this person familiar with the organization’s financial activities? Does your organization authorize this person to sign checks or handle cash?
6. Are all employees who handle funds required to be bonded against loss by reason of fraud or dishonesty?

K. Audit

1. What is your organization’s fiscal year?
2. Did the organization expend \$750,000 or more in Federal awards from all sources during its most recent fiscal year?
3. Has your organization submitted;
 - (a) an audit report to the ***Federal Audit Clearing House (FAC)*** in accordance with the Single Audit Act in the last 3 years? (see 45 CFR §75.501, “Audit requirements” and 45 CFR §75.216 “Special Provisions for Awards to Commercial Organization as Recipient.”) **or**
 - (b) an independent, external audit? If no, briefly explain. If yes, address the following:
 - i. The date of the most recently submitted audit report.
 - ii. The auditor's opinion on the financial statement.
 - iii. If applicable, indicate if your organization has findings in the following areas: 1) internal controls, 2) questioned or unallowable costs, 3) procurement/suspension and debarment, 4) cash management of award funds, and 5) subrecipient monitoring.
 - iv. Include (if applicable):
 1. A description of each finding classified as Material Weakness.

2. A description of each finding classified as Significant Deficiency.

4. Does the organization have corrective actions in the past 2 years for the findings identified above (3(iii))? If yes, describe the status (closed or open) and progress made on those corrective actions.

Appendix IV. Accessibility Requirements

CMS and its recipients are responsible for complying with federal laws regarding accessibility as noted in the Award Administration Information/Administration and National Policy Requirements Section.

The Recipient may receive a request from a beneficiary or member of the public for information in accessible formats. All successful applicants under this Notice of Funding Opportunity must comply with the following reporting and review activities regarding accessibility requests:

Accessibility Requirements:

1. Public Notification: If you have a public facing website, you shall post a message no later than **30** business days after award that notifies your customers of their right to receive an accessible format. Sample language may be found at: <https://www.medicare.gov/about-us/nondiscrimination/nondiscrimination-notice.html>. Your notice shall be crafted applicable to your program.
2. Processing Requests Made by Individuals with Disabilities:
 - a. Documents:
 - i. When receiving a request for information in an alternate format (e.g., Braille, Large print, etc.) from a beneficiary or member of the public, you must:
 1. Consider/evaluate the request according to civil rights laws.
 2. Acknowledge receipt of the request and explain your process within **2** business days.
 3. Establish a mechanism to provide the request.
 - ii. If you are unable to fulfill an accessible format request, CMS may work with you to provide the accessible format as funding and resources allow. You shall refer the request to CMS within **3** business days if unable to provide the request. You shall submit the request, using encrypted e-mail (to safeguard any personally identifiable information), to the AltFormatRequest@cms.hhs.gov mailbox with the following information:
 1. The e-mail title shall read “Grantee (Organization) Alternate Format Document Request.”
 2. The body of the e-mail shall include:
 - a. Requester’s name, phone number, e-mail, and mailing address.
 - b. The type of accessible format requested, e.g., audio recording on compact disc (CD), written document in Braille, written document in large print, document in a format that is read by qualified readers, etc.
 - c. Contact information for the person submitting the e-mail – Organization (Grantee), name, phone number and e-mail.
 - d. The document that needs to be put into an accessible format shall be attached to the e-mail.
 - e. CMS may respond to the request and provide the information directly to the requester.

iii. The Recipient shall maintain record of all alternate format requests received including the requestor's name, contact information, date of request, document requested, format requested, date of acknowledgment, date request provided, and date referred to CMS if applicable. Forward quarterly records to the AltFormatRequest@cms.hhs.gov mailbox.

b. Services

i. When receiving request for auxiliary aids and services (e.g., sign language interpreter) from a beneficiary or member of the public, you must:

1. Consider/evaluate the request according to civil rights laws.
2. Acknowledge receipt of the request and explain your process within **2** business days.
3. Establish a mechanism to provide the request.

ii. If you are unable to fulfill an accessible service request, CMS may work with you to provide the accessible service as funding and resources allow. You shall refer the request to CMS within **3** business days if unable to provide the service. You shall submit the request, using encrypted e-mail (to safeguard any personally identifiable information), to the AltFormatRequest@cms.hhs.gov mailbox with the following information:

1. The e-mail title shall read "Grantee (Organization) Accessible Service Request."
2. The body of the e-mail shall include:
 - a. Requester's name, phone number, e-mail, and mailing address.
 - b. The type of service requested (e.g., sign language interpreter and the type of sign language needed).
 - c. The date, time, address and duration of the needed service.
 - d. A description of the venue for which the service is needed (e.g., public education seminar, one-on-one interview, etc.)
 - e. Contact information for the person submitting the e-mail – Organization (Grantee), name, phone number and e-mail.
 - f. Any applicable documents shall be attached to the e-mail. CMS will respond to the request and respond directly to the requester.

iii. The Recipient shall maintain record of all accessible service requests received including the requestor's name, contact information, date of request, service requested, date of acknowledgment, date service provided, and date referred to CMS if applicable. Forward quarterly records to the AltFormatRequest@cms.hhs.gov mailbox.

3. Processing Requests Made by Individuals with Limited English Proficiency (LEP):

a. Documents:

i. When receiving a request for information in a language other than English from a beneficiary or member of the public, you must:

1. Consider/evaluate the request according to civil rights laws.
2. Acknowledge receipt of the request and explain your process within **2** business days.
3. Establish a mechanism to provide the request as applicable.

ii. If you are unable to fulfill an alternate language format request, CMS may work with you to provide the alternate language format as funding and

resources allow. You shall refer the request to CMS within **3** business days if unable to provide the request. You shall submit the request, using encrypted e-mail (to safeguard any personally identifiable information), to the AltFormatRequest@cms.hhs.gov mailbox with the following information:

1. The e-mail title shall read “Grantee (Organization) Alternate Language Document Request.”
2. The body of the e-mail shall include:
 - a. Requester’s name, phone number, e-mail, and mailing address.
 - b. The language requested.
 - c. Contact information for the person submitting the e-mail – Organization (Recipient), name, phone number and e-mail.
 - d. The document that needs to be translated shall be attached to the e-mail.
 - e. CMS may respond to the request and provide the information directly to the requester.

iii. The Recipient shall maintain record of all alternate language requests received including the requestor’s name, contact information, date of request, document requested, language requested, date of acknowledgment, date request provided, and date referred to CMS if applicable. Forward quarterly records to the AltFormatRequest@cms.hhs.gov mailbox.

b. Services

- i. When receiving request for an alternate language service (e.g., oral language interpreter) from a beneficiary or member of the public, you must:
 1. Consider/evaluate the request according to civil rights laws.
 2. Acknowledge receipt of the request and explain your process within **2** business days.
 3. Establish a mechanism to provide the request as applicable.

ii. If you are unable to fulfill an alternate language service request, CMS may work with you to provide the alternate language service as funding and resources allow. You shall refer the request to CMS within **3** business days if unable to provide the service. You shall submit the request, using encrypted e-mail (to safeguard any personally identifiable information), to the AltFormatRequest@cms.hhs.gov mailbox with the following information:

1. The e-mail title shall read “Grantee (Organization) Accessible Service Request.”
2. The body of the e-mail shall include:
 - a. Requester’s name, phone number, e-mail, and mailing address.
 - b. The language requested.
 - c. The date, time, address and duration of the needed service.
 - d. A description of the venue for which the service is needed (e.g., public education seminar, one-on-one interview, etc.)
 - e. Contact information for the person submitting the e-mail – Organization (Recipient), name, phone number and e-mail.
 - f. Any applicable documents shall be attached to the e-mail.
 - g. CMS will respond to the request and respond directly to the requester.

iii. The Recipient shall maintain record of all alternate language service requests received including the requestor's name, contact information, date of request, language requested, service requested, date of acknowledgment, date service provided, and date referred to CMS if applicable. Forward quarterly records to the AltFormatRequest@cms.hhs.gov mailbox.

Please contact the CMS Office of Equal Opportunity and Civil Rights for more information about accessibility reporting obligations at AltFormatRequest@cms.hhs.gov.

Appendix V. Merit Review and Selection Process

The review and selection process will include the following:

- i. Applications will be screened to determine eligibility for further review using the criteria detailed in Sections C. Eligibility Information, and D. Application and Submission Information (with cross-reference to Appendix II), of this NOFO. Applications that are received late or fail to meet the eligibility requirements as detailed in this NOFO or do not include the required forms will not be reviewed. However, the CMS/OAGM/GMO, in her or her sole discretion, may continue the review process for an ineligible application if it is in the best interest of the government to meet the objectives of the program.
- ii. Procedures for assessing the technical merit of grant applications have been instituted to provide for an objective review of applications based on merit and to assist the applicant in understanding the standards against which each application will be judged. The Review criteria described in Section E1. Criteria, will be used. Applications will be evaluated by a merit review committee. The merit review committee may include Federal and/or non-Federal reviewers. Applicants should pay strict attention to addressing all these criteria, as they are the basis upon which the reviewers will evaluate their applications.
- iii. The results of the merit review of the applications by qualified experts will be used to advise the CMS approving official. Final award decisions will be made by a CMS approving official. In making these decisions, the CMS approving official will take into consideration: recommendations of the merit review panel; the readiness of the applicant to conduct the work required; the scope of overall projected impact on the aims; reviews for programmatic and grants management compliance; the reasonableness of the estimated cost to the government and anticipated results; the geographic diversity of all applications; and the likelihood that the proposed project will result in the benefits expected.
- iv. As noted in 45 CFR Part 75, CMS will do a review of risks posed by applicants prior to award. In evaluating risks posed by applicants, CMS will consider the below factors as part of the risk assessment (applicant should review the factors in their entirety at §75.205)
 - a. Financial stability;
 - b. Quality of management systems and ability to meet the management standards prescribed;
 - c. History of performance (including, for prior recipients of Federal awards: timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous federal awards, extent to which previously awarded amounts will be expended prior to future awards);
 - d. Reports and findings from audits performed under Subpart F of 45 CFR Part 75 and
 - e. Applicant's ability to effectively implement statutory, regulatory, and other requirements imposed on non-federal entities.

v. CMS reserves the right to conduct pre-award Negotiations with potential recipients.

Appendix VI. Conflict of Interest

CMS requires recipients to establish safeguards to prevent employees, officers, or agents of the non-Federal entity such as consultants, contractors, members of governing bodies, and others who may be involved in grant-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial or other gain for themselves or others, such as those with whom they have family, business, or other ties. These safeguards must be reflected in written standards of conduct. Except as provided below, CMS does not require a recipient to establish separate standards of conduct if it maintains such standards for its non-grant-supported activities, as long as those standards are consistent with State, local, and tribal laws and regulations, and cover, at a minimum, expected conduct in regard to financial interests, gifts, gratuities and favors, nepotism, and such other areas for governmental organizations as political participation and bribery.

Definitions:

"Principal Investigator/Project Director (PI/PD)" means the individual(s) designated by the recipient to direct the project or program being supported by the grant. The PI/PD is responsible and accountable to officials of the recipient organization for the proper conduct of the project, program, or activity. This designation also includes co-principal investigators/co-project directors, and any other person at the organization who is responsible for the design, conduct, or reporting of grant activities funded or proposed for funding by CMS.

"Significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

This term does not include:

- a. salary, royalties or other remuneration from the applicant organization;
- b. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- c. income from service on advisory committees or review panels for public or nonprofit entities;
- d. an equity interest that, when aggregated for the PI/PD and the PI/PD's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or
- e. salary, royalties or other payments that, when aggregated for the PI/PD and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the prior twelve-month period.

The term "or other interest" means a non-financial benefit which results in a potential or real conflict of interest. The potential or real conflict of interest poses the same possible harms received from a financial conflict of interest such as bias due to personal gain. Such benefits may be received from a tangible or intangible personal benefit.

"Organizational conflicts of interest" means that because of relationships with a parent company, affiliate, or subsidiary organization, the non-Federal entity is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization.

“Responsible representative” means the individual(s), named by the applicant/recipient organization, who is authorized to act on behalf of the applicant/recipient and to assume responsibility for the obligations imposed by federal laws, regulations, requirements, and conditions that apply to CMS grant awards.

Requirements:

The majority of CMS’ grant programs are not supported by Public Health Service (PHS) funding; therefore, CMS is not subject to the requirements of 42 CFR Part 50, Subpart F, “Promoting Objectivity in Research.” Notwithstanding, CMS expects grant activities (including research activities) to be free from bias by any conflicting interest of the PI/PD and any other person regardless of title or position, who is responsible for the design, conduct, or reporting of grant activities which may include collaborators or consultants.

Recipient’s conflict of interest policies must reflect the following:

- Have a written and enforced administrative process to eliminate conflicting financial or other interests with respect to CMS grant/cooperative agreement funds awarded. This process should ensure:
 - The merits for determining a conflict of interest are clearly articulated in writing – i.e., the assigned reviewer(s) can reasonably determine that a significant or other interest could directly and significantly affect the design, conduct, or reporting of CMS-funded grant activities. This process should be inclusive of the appearance of such conflicts.
 - Each PI/PD discloses to a responsible representative of the Recipient all significant financial and/or other interests including personal relationships of the PI/PD (for example, PI/PD’s spouse, dependent children, etc.): (i) that would reasonably appear to be affected by the grant activities funded or proposed for funding by CMS; or (ii) in entities whose financial or other interests would reasonably appear to be affected by such activities.
 - One or more objective persons (1) reviews the potential conflict of interest; (2) determines whether a potential (appearance of) or real conflict of interest exists; and (3) Establishes what conditions, or restrictions, should be imposed to eliminate the conflict of interest.
 - This information is conveyed to the Responsible Representative for the organization who is designated to act on behalf of the applicable CMS award.
- Prior to expending funds under a new CMS award, the Responsible Representative must inform the applicable CMS Grants Management Specialist and Project Officer of any real or potential conflict of interest. The report must detail Recipient’s plan to eliminate the conflict prior to spending CMS funding on the activities in question.
- Require that similar reports for subsequently identified conflicts be made within 30 days of identifying them. Funding for those specific activities should cease until the aforementioned steps are completed.
- Require that continual updates be made for any real or potential conflicts of interest not fully resolved. Recipient must make additional information available to the CMS

Grants Management Specialist and Project Officer, upon request, as to how it is handling (or had handled) the real or potential conflict of interest.

- Recipients must maintain records of all disclosures and of all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any CMS action involving those records, whichever is longer.
- The Recipient's policy must include adequate enforcement mechanisms, and provide for sanctions where appropriate.

Recipient may resolve such conflicts of interest through one or more of the following options outlined below. This is not an exhaustive list and Recipient may pursue other remedies.

- Modification of approved project to remove potential or real conflict of interest.
- Termination of agreement or other services that create potential or real conflict of interest.
- Removal of individuals with potential or real conflict of interest.
- Severance of relationships that create potential or real conflicts of interest.
- Divestiture of significant financial interests.

Recipient must ensure that CMS award funds are administered in accordance with conflict of interest policies that meet, at a minimum, the standards outlined above, inclusive of pass-through entities, subrecipients, contractors, or collaborators. Each entity must have its own policies in place that meet these requirements or mandate that the PIs/PDs working for such entities follow those of the Recipient.

Procurement:

The Recipient must also maintain written standards of conduct covering conflicts of interest and governing the actions of its employees engaged in the selection, award and administration of contracts in accordance with **45 CFR §75.327 General procurement standards**. No employee, officer, or agent may participate in the selection, award, or administration of a contract supported by a Federal award if he or she has a real or apparent conflict of interest. Such a conflict of interest would arise when the employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in or a tangible personal benefit from a firm considered for a contract. The officers, employees, and agents of the non-Federal entity may neither solicit nor accept gratuities, favors, or anything of monetary value from contractors or parties to subcontracts. However, non-Federal entities may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value. The standards of conduct must provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the non-Federal entity.

If the non-Federal entity has a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe, the non-Federal entity must also maintain written standards of conduct covering organizational conflicts of interest.

Appendix VII. Application Check-off List

Required Contents

A complete application consists of the materials organized in the sequence below. Please ensure that the project and budget narratives are page-numbered and the below forms are completed with an electronic signature and enclosed as part of the application.

Everything listed below must be submitted through

<https://www.grants.gov/web/grants/home.html> and formatting requirements followed.

Documents without specific placeholders in the application kit available on Grants.gov should be uploaded under “Other Attachments Form.”

For specific requirements and instructions on application package, forms, formatting, please see:

- Section D and Appendix II: Application and Submission Information
- Section E: Application Review Information
- Appendix I: Guidance for Preparing a Budget Request
 - Required Forms/Mandatory Documents (with an electronic signature by AOR)
 - SF-424: Application for Federal Assistance
 - SF-424A: Budget Information
 - SF-424B: Assurances-Non-Construction Programs
 - SF-LLL: Disclosure of Lobbying Activities
 - Project Site Location Form(s)
 - Applicant’s Application Cover Letter (**excluded from page limitations**)
 - Project Abstract
 - Project Narrative
 - Business Assessment of Applicant Organization
 - Negotiated Indirect Cost Rate Agreement (NICRA)
 - Required Appendices
 - Key Staff Qualifications
 - Existing List of Research Projects and Roles
 - Letters of Agreement, Endorsement, or Support
 - Memoranda of Understanding/Agreements
 - Institutional Review Board (IRB) Approval Plan
 - Additional Supporting Documentation