U.S. Department of Health and Human Services

Office of Minority Health

Notice of Funding Opportunity: National Lupus Outreach and Clinical Trial Education Program

Opportunity Number: MP-CPI-23-003

Revised June 28, 2023 to correct period of performance on page 8 and to correct numbering of review criteria on page 34.

Application Due Date:
08/01/2023 at 6:00 PM Eastern

OVERVIEW

FEDERAL AGENCY NAME

The Office of the Assistant Secretary for Health, Office of Minority Health

FUNDING OPPORTUNITY TITLE

National Lupus Outreach and Clinical Trial Education Program

ACTION

Notice

ANNOUNCEMENT TYPE

Initial G (Grant)

FUNDING OPPORTUNITY NUMBER

MP-CPI-23-003

ASSISTANCE LISTING NUMBER AND PROGRAM:

93.137 , Community Programs to Improve Minority Health

DATES

Application Deadline: 08/01/2023 by 6:00 PM Eastern.

Technical Assistance Webinar: 06/27/2023 at 4:30 PM Eastern.

EXECUTIVE SUMMARY

The Office of Minority Health announces the availability of funds for Fiscal Year (FY) 2023 under the authority of 42 U.S.C. § 300u-6 (Section 1707 of the Public Health Service Act).

This notice solicits applications for projects to demonstrate the effectiveness of interventions for increasing racial and ethnic minority enrollment and retention in lupus-related clinical trials. Projects will identify and sustain effective interventions that advance clinical trial diversity and ultimately result in reduced lupus-related health disparities experienced by racial and ethnic minority populations. Increasing minority participation in lupus clinical trials is important for addressing lupus-related racial and ethnic health disparities. Recipients will sustain increased enrollment of racial and ethnic minorities in lupus-related clinical trials through outreach and education interventions, and public-private and community partnerships. Recipients also will assess the impact of project findings by implementing a process and outcomes evaluation for dissemination to diverse stakeholders.

The Office of Minority Health (OMH) has supported past initiatives focused on lupus education for health professionals, improving diagnosis and treatment, and increasing clinical trial diversity. These past OMH efforts will inform this initiative, using the education and outreach approaches previously developed to increase participation in clinical trials. OMH encourages recipients to use previously OMH-funded lupus interventions to build sustainable methods for increasing enrollment in lupus-related clinical trials through outreach and educational interventions and public-private community partnerships.

The Office of the Assistant Secretary for Health (OASH) encourages all applicants to review all program requirements, eligibility information, application format and submission information, evaluation criteria, and other information in this funding announcement to ensure that their applications comply with all requirements and instructions.

Table of Contents

A. Program Description

The Office of Minority Health announces the availability of funds for Fiscal Year (FY) 2023 under the authority of 42 U.S.C. § 300u-6 (Section 1707 of the Public Health Service Act).

We have supported programs to address lupus disparities since 2009. The lupus program has helped to improve lupus awareness, diagnosis, and treatment through increased collaboration among lupus organizations dedicated to research, education, support, and advocacy; improved outreach and education efforts in the community; and engagement of healthcare providers, educators, and health professions schools. This initiative will target individuals, patients, communities, and practicing professionals in geographic areas and populations where lupus is more prevalent. Under this initiative, we will continue to support the development of public-private partnerships with organizations representing lupus patients, implementation of effective interventions, and engagement of the lupus community to increase participation in lupus clinical trials for minority populations at highest risk.

1. Background

Lupus is a chronic autoimmune disease that causes inflammation in different tissues of the body, which leads to numerous clinical symptoms, and poses disease management and treatment challenges for patients and health care providers.[1] Normal functioning immune systems produce antibodies that protect against infection or foreign agents. In autoimmune disorders, such as lupus, the immune system cannot differentiate between foreign microorganisms and healthy tissue, which triggers the creation of autoantibodies that attack the body's healthy tissue, causing widespread inflammation as well as tissue and organ damage. The most common form of lupus is systemic lupus erythematosus (SLE), which affects different parts of the body including internal organs, joints, skin, brain, lungs, kidneys, and blood vessels.[2]

Although science continues to make significant advances in the treatment and management of this disease, the cause of lupus is unknown, and no cure exists. There is evidence of racial and ethnic disparities related to lupus, and differences by gender. African Americans are three to four times more likely to develop lupus than non-Hispanic whites.[3] A lupus study in California looked at four racial/ethnic groups: Blacks, whites, Asians/Pacific Islanders (APIs), and Hispanics. Findings indicated that Blacks, APIs, and Hispanics are at increased risk of developing severe symptoms and complications following SLE Diagnosis.[4] Other studies show that SLE rates among American Indians and Alaska Natives (AI/ANs) are similar or higher rates than rates among African Americans.[5] The onset of lupus may occur at any age, including among young children or the elderly; however, women of childbearing age (between 15 and 44 years old) are at the highest risk of onset.[6] Women are far more likely to have lupus than men at an estimated ratio of 12 to 1.[4] Women of color—African Americans, Hispanics/Latinos, AI/ANs, and APIs—are two to three times more likely to have lupus than white women.[7] Recent studies indicate that one in 537 young African American women have lupus.[7] Studies have demonstrated that minority women tend to develop lupus at a younger age, experience more serious complications, and have higher death rates from the disease.[7]

Clinical trials play a key role in identifying and developing new and better treatments for diseases, including lupus. Currently, there are approximately 400 sites seeking participation in lupus clinical trials in the U.S. and Canada.[8] Though many opportunities to participate in clinical trials exist, clinical trials for lupus have had limited success in recruiting minority participants.[9] This challenge is in line with the under-representation of racial and ethnic minority populations in clinical trials in general.[10] A recent study of national and international randomized controlled trials with lupus patients calculated that only 14 percent of those enrolled were Black, while Black people make up 43 percent of lupus cases. This same study noted that Black representation in randomized controlled trials in the US decreased between 2006 and 2011.[11] The Food and Drug Administration recommends that the participant pool in clinical trials reflect the demographics of the disease that the medical product is intended to treat.[12] Low minority participation in lupus clinical trials results in a lack of data on the effectiveness, safety, and side effects of treatment within populations with the highest incidence, prevalence, morbidity, and mortality.[13]

To increase participation in clinical trials, researchers have studied the barriers to participation in medical research. However, there are few evidence-supported interventions strategies or models to address the lack of minority participation in clinical trials. Studies exploring barriers to recruitment and enrollment have concluded the following factors contribute to the lack of clinical trial participation by minority populations: patient mistrust of the medical and research community, lack of access to health care, and lack of participant understanding clinical trials the benefits. Perceptions and biases of health care providers about minority participation and the lack of knowledge and awareness of clinical trials contributes to low minority participation. There are also logistical challenges that create barriers for participant referrals by providers.[10] Clinical trial sites are not in areas where minorities receive healthcare and clinic trial sponsors may not utilize voices in the community to recruit participants. Given these barriers, the adaption of interventions and models with strong evidence of engaging and increasing racial and ethnic populations in clinical trials have been found to be more viable and cost-effective options. Adaption not only can preserve the effectiveness of an intervention but also enhance the results that are reached in clinical trials.

2. Expectations for Funded Projects

Funded projects should meet the following expectations:

a. Develop Public-Private and Community Partnerships

We expect recipients to utilize standard practices necessary for establishing and sustaining effective collaborative partnerships, including public-private and community partnerships. This includes developing a structure for regularly engaging community and partnering organizations in the design and review of outreach or education interventions to be tested through their project. Recipients should leverage the strengths of each partner organization. Partners may also play a role in sustaining the project after the award ends, and in supporting and/or sustaining effective practices to increase racial and ethnic minority enrollment and retention in lupus clinical trials.

Recipients should implement a project that involves at least two collaborative partnerships with at least two different organizations. One of the organizations must be a:

- Local hospital, health care system, Federally Qualified Health Center (FQHC), or community health center;
- National, state, or local professional organization that represents primary care physicians, other health care providers, and/or Community Health Workers;
- An organization with experience recruiting minority participants into clinical trials; or
- A Tribe or tribal organization.

We strongly encourage recipients to engage community-based organizations (CBOs) in their project implementation as appropriate.

b. Adaptation of Existing Interventions

We encourage recipients to adapt an existing OMH-funded intervention (Section I.5) to increase minority participation in clinical trials for the intended population of focus, while maintaining the fidelity of the original intervention. Fidelity refers to the degree to which an implementer adheres to the core components of the intervention. We also expect recipients to implement the adapted intervention and ensure the sustainability of the improved results. Recipients should implement the adapted intervention(s) in racial and ethnic minority communities within cities and/or counties where lupus clinical trials are recruiting patients (for current trials, see Section I.6). Interventions may include:

- **Education models** that improve attitudes and practices of health care providers and paraprofessionals to increase racial and ethnic minority enrollment and retention in lupus clinical trials;
- **Outreach and social media campaigns** on lupus clinical trials aimed toward racial and ethnic minority individuals;
- **Capacity-building models** designed to recruit, enroll and retain participants in clinical trials and patient-centered, culturally appropriate clinical trial education models.

c. Demonstrate Increased Enrollment in Lupus Clinical Trials

We expect recipients to demonstrate the extent to which the project has increased the number of participants recruited, screened, and enrolled into lupus clinical trials. Including diverse racial and ethnic populations in lupus clinical trials will ensure that treatment approaches and outcomes reflect the reality of the disease among various groups, thereby promoting health equity and facilitating a better understanding of the disease.

d. Implement a Process and Outcomes Evaluation

We expect projects to implement a rigorous evaluation to assess the impact of project activities. Recipients should implement a process and outcomes evaluation that assesses the extent to which the intervention increased racial and ethnic minority referrals, enrollment, and/or retention in lupus clinical trials. In addition to this measure, recipients should measure lupus clinical trial knowledge

of healthcare providers/community health workers and measure attitudes, knowledge and beliefs gained using pre- and post-surveys. The evaluation should also assess the continued effectiveness of adapted interventions, fidelity, and any differential effects based on the adaptation approach.

The evaluation plan should clearly demonstrate that evaluation of the impact of the intervention will be able to detect a statistically significant difference in key project outcomes, if such an impact is present. The evaluation design should control for threats to validity, including effect size. We expect the impact analysis of the intervention to be conducted within the period of performance.

e. Document and Disseminate Project Findings

We anticipate recipients will develop new knowledge about existing interventions that increase minority populations' participation in lupus clinical trials. Recipients should document project knowledge and findings, to include implementation process, lessons learned, successes and challenges. We expect recipients to communicate and disseminate project knowledge and findings, to include dissemination to federal, state, territorial and tribal public health agencies; policymakers; community organizations; community members; and other stakeholders. All appropriate findings and products may be posted on an HHS/OMH sponsored website (Section F.9). We expect that nationwide dissemination of products and knowledge will occur. When published, materials should be freely, immediately, and equitably accessible to the public.

f. Develop a Disparity Impact Statement

Recipients should develop a disparity impact statement (DIS) during the project period using local data to identify populations at highest risk for health disparities relative to this initiative. Additional information and links to resources are available in Section I.2.

B. Federal Award Information

1. Legal Authority

42 U.S.C. § 300u-6 (Section 1707 of the Public Health Service Act)

2. Award Information

We intend to make funds available for competing G (Grant) awards.

We will fund awards in annual increments and generally for a period of performance up to 3 year(s), although we may approve shorter periods of performance. Budget periods may also vary from the estimate indicated below due to timing of award issuance or other administrative factors.

Recipients will be required to submit a non-competing continuation application for each budget period after the first. Funding for all approved budget periods beyond the first is generally level with the initial award amount and is contingent upon the availability of funds, satisfactory

progress of the project, adequate stewardship of Federal funds, and the best interests of the Government.

Award Information

Estimated Federal Funds Available	$2,000,000
Anticipated Number of Awards	6
Award Ceiling (Federal Funds including indirect costs)	$500,000 per budget period
Award Floor (Federal Funds including indirect costs)	$300,000 per budget period
Anticipated Start Date	09/01/2023
Estimated Period of Performance	Not to exceed 3 year(s)
Anticipated Initial Budget Period Length	12 months
Type of Award	Grant
Type of Application Accepted	Electronic via Grants.gov ONLY unless an exemption is granted.

C. ELIGIBILITY INFORMATION

1. Eligible Applicants

Any public or private nonprofit entity located in a State (which includes one of the 50 United States, District of Columbia, Commonwealth of Puerto Rico, U.S. Virgin Islands, Commonwealth of the Northern Mariana Islands, American Samoa, Guam, Republic of Palau, Federated States of Micronesia, and the Republic of the Marshall Islands) is eligible to apply for an award under this announcement.

Faith-based organizations and American Indian/Alaskan Native/Native American (AI/AN/NA) organizations that are public or non-profit private entities are eligible to apply.

Public or non-profit community-based organizations (CBOs) are eligible to apply.

Non-profit private institutions of higher education are eligible to apply.

Other examples of eligible Organizations include:

State governments

County governments

City or township governments

Special district governments

Independent school districts

Public and State controlled institutions of higher education

Native American tribal governments (Federally recognized)

Public housing authorities/Indian housing authorities

Native American tribal organizations (other than Federally recognized tribal governments)

Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education

Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education

2. Cost Sharing or Matching

You are not required to provide cost sharing or matching in your proposed budget. If you voluntarily include cost sharing in your application, you must include in your budget narrative a non-federal sources justification as described in Section D.3.b.1.t or your application will be disqualified (Section C.4.k). Voluntary cost sharing is not expected for research applications. During the merit review of an application, cost sharing will only be considered in the overall review of the adequacy of the total proposed budget (Federal and non-Federal share) to support the project proposed.

Applications including cost sharing or matching, whether required or voluntary, that result in an award will include the cost sharing or matching commitment on the notice of award at the level proposed in the application. See Section D.3.b.1.s. Any change in the responsibility to provide cost sharing or matching at that level will require prior approval of the grants management officer.

Cost-Sharing or Matching may include any in-kind contributions necessary to the execution of the proposed project (45 C.F.R. § 75.306).

3. Other - Application Responsiveness Criteria

We will review your application to determine whether it meets the responsiveness criteria below. If your application does not meet the responsiveness criteria, we will disqualify it from the competition; we will not review it beyond the initial screening. The responsiveness criteria are as follows

There are no Other - Application Responsiveness Criteria.

4. Application Disqualification Criteria

If you successfully submit an application, the OASH Grants and Acquisitions Management (GAM) Division will determine whether your application is eligible according to section C.1 Eligible Applicants. If we determine your application fails to meet the criteria described below, we will disqualify it, that is, **we will not review it and will give it no further consideration**.

a. You must submit your application electronically via https://grants.gov/ (unless an exemption was granted by the grants management officer 2 business days prior to the deadline) by the date and time indicated in Section D.5 of this announcement.

b. If you successfully submit multiple applications from the same organization for the same project, we will only review the last application received by the deadline.

c. You must complete the required forms in the application package: SF-424, SF-424A, SF-LLL, and Project Abstract Summary (Section D.2.a).

d. Your application must be submitted in the English language and must be in terms of U.S. dollars (45 C.F.R. § 75.111(a)).

e. Your Project Narrative section of the application must be double-spaced, on the equivalent of 8 ½ ” x 11” page size, with 1” margins on all sides (top, bottom, left and right) and font size not less than 12 points (Section D.2.a).

f. Your Project Narrative must not exceed 60 pages. The following items do not count toward the Project Narrative page limit: all required forms, including SF-424, SF-424A, SF-LLL, Project Abstract Summary, and Budget Narrative (including budget tables)(Section D.2.a).

g. Your total application (i.e., the Project Narrative plus Appendices) must not exceed 80 pages. The following items do not count toward the Project Narrative page limit: all required forms, including SF-424, SF-424A, SF-LLL, Project Abstract Summary, and Budget Narrative (including budget tables)(Section D.2.a).

h. Your Federal funds request including indirect costs must not be above the maximum indicated in Award Ceiling (Section B.2).

i. Your Federal funds request including indirect costs must not be below the Minimum indicated in Award Floor, if any (Section B.2).

j. Your application must meet the Other - Application Responsiveness Criteria outlined above (Section C.3).

k. If your application includes cost sharing (voluntary or required, Section C.2), you must include in your budget narrative a non-federal sources justification.

D. APPLICATION AND SUBMISSION INFORMATION

1. Address to Request Application Package

You may obtain an application package electronically by accessing Grants.gov at https://www.grants.gov/. You can find it by searching on the Assistance Listing (formerly CFDA) number shown on page 1 of this funding opportunity announcement. If you have problems accessing the application or difficulty downloading, contact:

OASH Grants and Acquisitions Management Division

Phone: 240-453-8822

Email: OASH_Grants@hhs.gov

2. Content and Form of Application Submission

a. Application Format

Your application must be prepared using the forms and information provided in the online application package. This includes but is not limited to:

- SF-424 Application for Federal Assistance
- SF-424A Budget Information for Non-Construction Programs
- SF-LLL Disclosure of Lobbying Activities
- Project Abstract Summary

We encourage individuals to use their full name (first, middle, last) on the Standard Forms and other documents such as résumés/curricula vitae/biographical sketches to distinguish them for verification in the System for Award Management exclusion records. Delays may result in award processing if full names are not provided.

Only one Project Director/Principal Investigator (PD/PI) will be named on any resulting award. You should clearly identify the individual in that role in your application. This individual should be the person who will be responsible for the programmatic aspects of the project if an award is made. A placeholder PD/PI is strongly discouraged because this may not present a clear picture for the review. Furthermore, once an award is issued a request for a change in PD/PI requires prior approval of the grants management officer (45 C.F.R. § 75.308(c)(1)(ii-iii)).

The Project Narrative, and total application including appendices, must adhere to the page limit indicated in Application Disqualification Criteria listed in Section C.4. The page limit does not include the Budget Narrative (including budget tables), required forms, assurances, and certifications as described in the Application Disqualification Criteria.

You must double-space the Project Narrative pages.

Your application must be submitted in the English language and must be in the terms of U.S. dollars (45 C.F.R. § 75.111(a))

You should use an easily readable typeface, such as Times New Roman or Arial. You ***must*** use 12-point font. You may single-space tables or use alternate fonts, but you must ensure the tables are easy to read.

Please do not number pages or include a table of contents. Our grants management system will generate page numbers once your application is complete. If your application exceeds the specified page limits for the Project Narrative or Project Narrative plus Appendices (Section C.4(f)-(g)) when printed on 8.5" X 11" paper as determined by OASH/GAM, the application will not be reviewed further. We recommend you print out your application before submitting electronically to ensure that it is within the page limits and is easy to read.

b. Appendices Format

Your appendices should include any specific documents outlined in Section D.3.c, under the heading "Appendices" in the Application Content section of this announcement. Your documents should be easy to read. You should use the same formatting specified for the Project Narrative. However, documents such as résumés/curricula vitae, organizational charts, tables, or letters of commitment may use formatting common to those documents, but the pages must be easy to read. All of your appendices must be uploaded as a single, consolidated file in the Attachments section of your Grants.gov application.

c. Project Abstract Summary Format

You must complete the Project Abstract Summary form provided in the application package. The abstract will be used to provide reviewers with an overview of the application and will form the basis for the application summary in grants management and program summary documents. Furthermore, if your project is funded, HHS will publish the abstract from your form on TAGGS.hhs.gov and USASpending.gov. The abstract may also appear on the program office website or other government website. Therefore, do not include sensitive or proprietary information in your abstract.

d. Budget Narrative Format

The Budget Narrative should use the formatting required of the Project Narrative for the explanatory text. Budget tables may be single-spaced but should be laid out in an easily-readable format and within the printable margins of the page.

3. Application Content

Successful applications will contain the following information:

a. Project Narrative Content

The Project Narrative is the most important part of the application, since it will be used as the primary basis to determine whether your project meets the minimum requirements for an award under this announcement. The Project Narrative should provide a clear and concise description

of your project. We recommend that your project narrative include the following components: 1) Significance of the Project; 2) Goals, Objectives, and Outcomes; 3) Project Plan; 4) Organizational Capability; 5) Evaluation Plan; and 6) Dissemination Plan.

1) Significance of the Project

Describe how you envision the project will benefit the field, targeted population, and society (i.e., significance of the project). Using quantitative data, describe the significance of your project in meeting the need for increasing enrollment in of clinical trial participants within your intended population(s) and geographic area(s) of focus to address the disproportionate impact of lupus on racial and ethnic minority populations. Refer to the population of focus data provided in your appendices (Section D.3.c.3) as appropriate. Your description should identify the contributing factors to the disproportionate impact addressed by your project. Describe the specific barriers to your focus population's participation in clinical trials. Describe how the project will potentially affect the populations served, specific subgroups within those populations, and other identified interested stakeholders. Also describe the anticipated importance, supported by data, for public-private partnerships and community partnerships to support and sustain project activities.

2) Goals, Objectives, and Outcomes

Describe the overall project goals, annual short-term and long-term objectives, and outcomes. We will not fund any project that does not include measurable outcomes. A “measurable outcome” is an observable end-result that describes how a particular intervention benefits program participants. It demonstrates the “impact” of the intervention.

Provide a sufficient description of the magnitude of impact on intervention outcomes and performance measure objectives for the proposed activities. Your objectives should be SMARTIE (specific, measurable, attainable, relevant, time-bound, inclusive, equitable). SMARTIE objectives should include baseline data and quantifiable time-frames for achievement. Objectives should focus on overall goals of the project rather than project activities. Intervention objectives should describe the overall goals of the project rather than project activities. Goals must be ambitious and achievable in the project's time-frame. This section should clearly identify the measurable outcome(s) that will result from the project, and provide a specific, quantified estimate of the expected outcome(s).

Your objectives and outcomes should align with your vision of how the project will benefit the field, targeted population, and society (i.e., significance of the project).

3) Project Plan

In reference to your work plan in your appendices (Section D.3.c.1), provide a detailed summary of activities to be undertaken, and how those activities will assist in achieving the project goals and objectives including increasing minority participation in lupus-related clinical trials. Explain the rationale for the lupus intervention you selected (previously OMH-funded interventions encouraged), and present a clear connection between any identified evidence gaps, needs, and the

proposed project activities. Describe how the intervention will be tailored for the population(s) of focus while maintaining fidelity to its core components. Also describe specific practices you will use in your project to address the contributing factor(s) your proposal addresses. Identify any major barriers anticipated and how the project will be able to overcome those barriers.

Describe the approach and rationale for recruiting, enrolling, and retaining participants. Also describe how the approach will increase the number of participants, recruited, screened, and enrolled into lupus clinical trials. Describe how your project will increase provider and/or minority participation and address barriers to minority participation in lupus clinical trials. Describe the proposed approach for developing public-private and community partnerships and related activities, and the rationale behind the strategies that will be used to work with partners to achieve the project goals.

This section should describe how the proposed intervention is culturally and linguistically appropriate for the population of focus. Describe how you will apply the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (National CLAS Standards)(https://thinkculturalhealth.hhs.gov/clas/standards) to facilitate your project.

Describe the approach that you will use to monitor progress on the tasks and objectives. Describe how you will use data collected over the course of your project to support quality improvement and ensure the project is implemented in a culturally appropriate manner over the full period of performance.

4) Organizational Capacity

Describe your organizational readiness to implement the intervention(s) or practice(s).

Describe how your organization (or your division of a larger agency responsibile for this project) is organized, the nature and scope of its work, and the capabilities it possesses. Describe any current or previous relevant experience, including any significant experience relative to the inclusion of minority populations in clinical trials. Describe any experience and expertise in providing outreach to and education of minority populations; clinical trial outreach to increase enrollment; evaluation of outreach education and training program related to recruitment, participation and retention in clinical trials; and working with individuals and families of people living with lupus. If relevant to your selected intervention, include experience working with CHWs and other patient advocates and their role in outreach, education, and training related to recruitment and participation in clinical trials.

Describe the organization's history of forming, managing, and engaging community and partnering organizations in the conduct of health-related initiatives. Describe your existing public-private and community partnerships relevant to this project, and identify partner roles and responsibilities in reference to any submitted memoranda of agreement (MOAs)(Section D.3.c.#). Describe your readiness for implementing the project and achieving measurable outcomes in the period of performance.

Describe areas of expertise for key personnel in reference to the vitae, resumes, or biographical sketches you submit (Section D.3.c.#). At a minimum, key personnel includes the Program

Director/Principal Investigator who will have day to day oversight of the project. You should identify the specific knowledge and expertise on issues related to clinical trials to support developing and implementing effective outreach or education interventions regarding lupus clinical trials. You should also identify the significant knowledge and expertise in lupus epidemiology, diagnosis, treatment, and disparity-related issues.

Key Personnel includes those individuals in roles who will oversee the technical, professional, managerial, and essential support functions and/or assume responsibility for assuring the validity and quality of your organization's project. Key personnel does not include individuals who provide routine administrative support to the project as part of their broader support of the organization.You should describe the qualifications, competing time commitments, and related ongoing projects of all key personnel. Identify the individuals/organizations responsible for evaluation activities and their qualifications. Describe the relationship between the evaluator and your organization and the degree of independence the evaluator will have.

Reference the organizational chart in your appendices (Section D.3.c.#). This chart should include the contractual and/or supportive organizations that will become part of the network. Describe any contractual and/or supportive staff/organization(s) that will have a secondary role(s) in implementing the project and achieving project goals should be included.

5) Evaluation Plan

Provide a process and outcomes evaluation plan for the project describing the evaluation approach you will use to determine whether the project reaches its population(s) of focus. Your evaluation plan should demonstrate the equity impact of the project on the identified health disparities. Your evaluation design should clearly establish whether project activities result in the intended outcome(s). The evaluation design must demonstrate controls for threats to validity and the ability to show a statistically significant impact of your intervention on the key outcomes.

Identify the data you will collect and use to monitor and document key project outcome(s), detailing the validity and reliability of proposed measures/indicators. Describe the methods you will use to collect your data, including performance measurement data, and how you will overcome any potential obstacles to data collection.

Include your approach to collecting, at minimum, baseline, interim, and post-intervention process and outcome measures. Describe how you will evaluate all project components of the project's logic model (Section D.3.c.2), including how the inputs, processes, outputs, and outcomes will be measured. Describe how you will assess the extent to which the intervention(s) increased racial and ethnic minority enrollment and retention in lupus clinical trials. Describe any involvement of your partners in the evaluation activities. .

6) Dissemination Plan

Describe the method you will use to disseminate the project's results and findings on time and in easily understandable formats to the population served, the general public, and other parties interested in using the project results. In addition to traditional forms of dissemination such as scholarly articles in peer review journals, we encourage you to propose innovative approaches to

informing those who might be interested in using the results of your project. Dissemination efforts should focus on assisting those you may replicate your project. All relevant findings and products may be posted on an HHS/OMH- sponsored website as determined by HHS/OMH. See also Section F.9.

b. Budget Narrative Content

You must complete the required budget forms and submit a budget narrative with detailed justification as part of your application. You must enter the project budget on the Budget Information Non-construction Programs standard form (SF-424A) according to the directions provided with this standard form. The budget narrative consists of a detailed line-item budget that includes calculations for all costs and activities by "object class categories" identified on the SF-424A and justification of the costs.

Project budget calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient to verify the calculations. If matching or cost sharing is required, you must include a detailed listing of any funding sources identified in box 18 of the SF-424 (Application for Federal Assistance). You must state the method you are selecting for your indirect cost rate. See Indirect Costs (Section D.3.b.1.o)) for further information. If you are providing in-kind contributions of any type or value, including costs otherwise covered by your indirect cost rate, you must identify those costs, and you should, as appropriate, include the value of the in-kind contribution as proposed cost-sharing (voluntary or required) (45 C.F.R. § 75.306).

Please be sure to carefully review Section D.7 Funding Restrictions for specific information regarding allowable, unallowable, and restricted costs.

You must provide an object class category budget using Section B, box 6 of the SF-424A for the first year of the proposed project. For awards with an anticipated period of performance of one year or less, this will be the budget request for the entire project. Provide a budget justification, which includes explanatory text and line-item detail, for the entire first year of the proposed project. The budget narrative should describe how the categorical costs are derived. Discuss the necessity, reasonableness, and allocation of the proposed costs.

For subsequent budget years in an anticipated multi-year project, provide a summary narrative and line-item budget for each year beyond the first. For categories or items that differ significantly from the first budget year, provide a detailed justification explaining these changes.

Do not include costs beyond the first budget period in the object class budget in box 6 of the SF-424A or box 18 of the SF-424; the amounts entered in these sections should only reflect the first budget period.

Your budget narrative should justify the overall cost of the project as well as the proposed cost per activity, service delivered, and/or product. For example, the budget narrative should define the amount of work you have planned and expect to perform, what it will cost, and an explanation of how the result is cost effective. If you are proposing to provide services to clients, you should describe how many clients you expect to serve, the unit cost of serving each client, and how this is cost effective.

Use the following guidelines for preparing the detailed object class budget required by box 6 of the SF-424A. The object class budget organizes your proposed costs into a set of defined categories outlined below. Both federal and non-federal resources (if applicable) must be detailed and justified in the budget narrative. "Federal resources" refers only to the HHS/OASH funds for which you are applying under this NOFO. "Non-federal resources" are all other non-HHS/OASH federal and non-federal resources. We recommend you present budget amounts and computations in a columnar format: first column, object class categories; second column, federal funds requested; third column, non-federal resources; and last column, total budget.

Object Class	Federal Funds Requested	Non-federal Resources	Total Budget
Personnel	$100,000	$25,000	$125,000

Subrecipient/contract and consultant detailed costs should all be included in those specific line items, not in the overall project object class line items. For example, subrecipient travel should be included in the Contractual line item not in Travel. **Subrecipient/contract and consultant activities must be described in sufficient detail to describe accurately the project activities that each will conduct**.

1. Object Class Descriptions and Required Justifications

a. **Personnel Description**

Costs of staff salaries and wages, excluding benefits.

b. **Personnel Justification**

Clearly identify the PD/PI, if known at the time of application. Provide a separate table for personnel costs detailing for each proposed staff person: the title; full name (if known at time of application), time commitment to the project as a percentage or full-time equivalent: annual salary and/or annual wage rate; federally funded award salary; non-federal award salary, if applicable; and total salary. No salary rate may exceed the statutory limitation in effect at the time you submit your application (see D.7.2) Funding Restrictions, *Salary Rate Limitation* for details). Do not include the costs of consultants, personnel costs of delegate agencies, or of specific project(s) and/or businesses to be financed by the applicant. **Contractors and consultants should not be placed under this category**.

Position Title and Full Name	Percent Time	Annual Salary	Federally-funded Salary	Non-federal Salary	Total Project Salary
Project Director, John K. Doe	50%	$100,000	$50,000	$0	$50,000
Data Assistant,	10%	$30,000		$3,000	$3,000

Position Title and Full Name	Percent Time	Annual Salary	Federally-funded Salary	Non-federal Salary	Total Project Salary
Susan R. Smith					

c. **Fringe Benefits Description**

Costs of employee fringe benefits unless treated as part of an approved indirect cost rate.

d. **Fringe Benefits Justification**
Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, Federal Insurance Contributions Act (FICA) taxes, retirement insurance, and taxes.

e. **Travel Description**
Costs of travel by staff of the applicant organization only. **Do not** include travel costs for subrecipients or contractors under this object class.

f. **Travel Justification**
For each trip proposed for applicant organization staff only, show the date of the proposed travel, total number of traveler(s); travel destination; duration of trip; per diem; mileage allowances, if privately owned vehicles will be used; and other transportation costs and subsistence allowances. **Do not** include travel costs for subrecipients or contractors under this object class.

g. **Equipment Description**
Equipment means tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-Federal entity for financial statement purposes, or $5,000. (Acquisition cost means the cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non-Federal entity's regular accounting practices.) See 45 C.F.R. § 75.2 for additional information.

h. **Equipment Justification**
For each type of equipment requested you must provide a description of the equipment; the cost per unit; the number of units; the total cost; and a plan for use of the equipment in the project; as well as a plan for the use, and/or disposal of, the

equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy, or section of its policy, that includes the equipment definition; include this with your Budget Narrative file. Reference the policy in this justification and include the policy copy in your Budget Narrative file (not your appendices).

i. **Supplies Description**

Costs of all tangible personal property other than those included under the Equipment category. This includes office and other consumable supplies with a per-unit cost of less than $5,000.

j. **Supplies Justification**
Specify general categories of supplies and their costs. Show computations and provide other information that supports the amount requested.

k. **Contractual Description**

Costs of all contracts or subawards for services and goods except for those that belong under other categories such as equipment, supplies, construction, etc. Include third-party evaluation contracts, if applicable, and contracts or subawards with subrecipient organizations (with budget detail), including delegate agencies and specific project(s) and/or businesses to be financed by the applicant. **This line item is not for individual consultants.**

l. **Contractual Justification**

Demonstrate that all procurement transactions will be conducted in a manner to provide, to the maximum extent practical, open, and free competition. Recipients and subrecipients are required to use 45 C.F.R. § 75.329 procedures and must justify any anticipated procurement action that is expected to be awarded without competition and exceeds the simplified acquisition threshold fixed by 41 U.S.C. § 134 and currently set at $250,000. Recipients may be required to make pre-award review and procurement documents, such as requests for proposals or invitations for bids, independent cost estimates, etc., available to HHS/OASH.

Whenever you intend to transfer a substantive part of the project effort to another entity (including non-employee individuals), you must provide a detailed budget and budget narrative for each subrecipient/contractor, by title/name, along with the same supporting information referred to in these instructions. If you plan to select the subrecipients/contractors post-award and a detailed budget is not available at the time of application, you must provide information on the nature of the work to be transferred, the estimated costs, and the process for selecting the subrecipient/contractor.

m. **Other Description**

Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to: consultants; insurance; professional services (including audit charges); space and equipment rent; printing and publication; training, such as

tuition and stipends; participant support costs including incentives, staff development costs; and any other costs not addressed elsewhere in the budget.

n. **Other Justification**

Provide computations, a narrative description, and a justification for each cost under this category.

o. **Indirect Costs Description**

Total amount of indirect costs. This category has one of two methods that you may select. You may only select one and must clearly identify that selection in your submitted budget.

- Your organization currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant federal agency. You should enclose a copy of the current approved rate agreement in your Budget Narrative file. If you request a rate that is less than allowed, your authorized representative must submit a signed acknowledgement that the organization is accepting a lower rate than allowed.
- Per 45 C.F.R. § 75.414 (f) Indirect (F&A) costs, "any non-Federal entity [i.e., applicant] that has never received a negotiated indirect cost rate, … may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. As described in § 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time."

The de minimis rate method only applies if you have never received an approved negotiated indirect cost rate from HHS or another cognizant federal agency. If you are waiting for approval of an indirect cost rate, you may request the 10% de minimis rate. If you choose this method, costs included in the indirect cost pool must not be charged as direct costs to the award.

Indirect costs on Federal awards for training are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000 (45 C.F.R. § 75.414 (c)(1)(i)).

p. **Indirect Costs Justification**

Provide the calculation for your indirect costs total, i.e., show each line item included in the base, the total of these lines, and the application of the indirect rate. If you have multiple approved rates, indicate which rate as described in your approved agreement is being applied and why that rate is being used. For example, if you have both on-campus and off-campus rates, identify which is being used and why.

q. **Program Income Description**

Program income means gross income earned by your organization that is directly generated by this project if funded except as provided in 45 C.F.R. § 75.307(f). Program income includes but is not limited to income from fees for services performed or the use or rental of real or personal property acquired under the award. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See also 45 C.F.R. § 75.307 and 35 U.S.C. §§ 200-212 (applies to inventions made under Federal awards).

r. **Program Income Justification**

Describe and estimate the sources and amounts of program income that this project may generate, if funded. All program income generated as a result of awarded funds must be used within the scope of the approved project-related activities. Any program income earned by the recipient must be used under the addition/additive method unless otherwise specified in Section C.2. These funds should not be added to your budget, unless you are using the funds as cost sharing or matching, if applicable. This amount should be reflected in box 7 of the SF-424A.

s. Non-Federal Resources Description

Amounts of non-federal resources that will be used to support the project as identified in box 18 of the SF-424. For all federal awards, any shared costs or matching funds and all contributions, including cash and third-party in-kind contributions, must be accepted as part of the recipient's cost sharing or matching when such contributions meet all of the criteria listed in 45 C.F.R. § 75.306.

For awards that require matching by statute, you will be held accountable for projected commitments of non-federal resources in your application budgets and budget justifications by budget period or by period of performance for fully-funded awards, even if the justification by budget period, or by period of performance for fully-funded awards, exceeds the amount required. Your failure to provide the required matching amount may result in the disallowance of federal funds. If you are funded, you will be required to report these funds on your Federal Financial Reports.

For awards that do not require matching or cost sharing by statute or regulation, where "cost sharing" refers to costs of a project in addition to Federal funds requested that you voluntarily propose in your budget, if your application is successful, we will include this non-federal cost sharing in the approved project budget and you will be held accountable for the non-federal cost-sharing funds as shown in the Notice of Award (NOA). Failure to meet a cost sharing or matching obligation that is part of the approved project budget on the NOA may result in the disallowance of federal funds.

If you are funded, you will be required to report cost sharing or matching funds on your quarterly Federal Financial Reports. You will not receive any preference,

priority, or special consideration in the funding process for voluntarily including non-Federal cost sharing in your proposed budget.

t. **Non-Federal Resources Justification**

You must provide detailed budget information for every funding source identified in box 18. "Estimated Funding ($)" on the SF-424. Provide this documentation as part of your Budget Narrative file, not your Appendices.

You must fully identify and document in your application the specific costs or contributions you propose in order to meet a matching requirement. You must provide documentation in your application on the sources of funding or contribution(s). In-kind contributions must be accompanied by a justification of how the stated valuation was determined. Matching or cost sharing must be documented by budget period (or by period of performance for fully-funded awards).

Unrecovered indirect costs may be included as part of your cost sharing or matching only with prior approval of the grants management officer. Your budget narrative must clearly state that it is your intent to include unrecovered indirect costs as part of your cost sharing or matching. You should include a copy of your negotiated cost rate to support the justification. Unrecovered indirect cost means the difference between the amount charged to the Federal award and the amount which could have been charged to the Federal award under your approved negotiated indirect cost rate. (See 45 C.F.R. § 75.306(c)).

If your application does not include the required supporting documentation for required or voluntary cost-sharing or matching, it will be disqualified from competitive review (Section C.4(k)).

2. **Plan for Recipient Oversight of Federal Award Funds**

You must include a plan for oversight of federal award funds which describes:

- how your organization will provide oversight of federal funds and how award activities and partner(s) will adhere to applicable federal award and programmatic regulations. Include identification of risks specific to your project as proposed and how your oversight plan addresses these risks.
- the organizational systems that demonstrate effective control over and accountability for federal funds and program income, compare outlays with budget amounts, and provide accounting records supported by source documentation.
- for any program incentives proposed, the specific internal controls that will be used to ensure only qualified participants will receive them and how they will be tracked.
- organizational controls that will ensure timely and accurate submission of Federal Financial Reports to the OASH Grants and Acquisitions Management Division via the Payment Management System as well as timely and appropriate withdrawal of cash from the Payment Management System.

If your internal controls are available online, it is recommended that you provide the link as part of your plan in the budget narrative. We have also included supplementary information in Section I.1, which contains questions applicants may find useful in considering their Recipient Plans for Oversight of Federal Funds.

c. Appendices

All items described in this section will count toward the total page limit of your application. You must submit them as **a single electronic file** uploaded to the Attachments section of your Grants.gov application.

1. Work Plan

Your Work Plan should reflect, and be consistent with, the Project Narrative and Budget Narrative, and must cover all years of the period of performance. However, each year's activities should be fully attainable in one budget year. You may propose multi-year activities, as well as activities that build upon each other, but each phase of the project must be discreet and attainable within a single budget year. Your Work Plan should include a statement of the project's overall goal, anticipated outcome(s), key objectives, and the major tasks, action steps, or products that will be pursued or developed to achieve the goal and outcome(s). For each major task of each year, action step, or product, your work plan should identify the time-frames involved (including start- and end-dates), and the lead person responsible for completing the task.

An optional Objective Work Plan (OWP) template is provided in the application materials on grants.gov (the 3 instruction pages will not count toward your page limit) or you may create your own work plan. Regardless of the option you choose, the work plan you submit must address all the content requested.

2. Logic Model

You should submit a detailed logic model that describes the inputs, objectives, activities, outputs, and short- and long-term outcomes of the intervention being tested through the proposed project. All program objectives, activities, and anticipated outcomes shall be reflected in the logic model and demonstrate that the proposed project reflects a coherent approach.

3. Project Population(s) of Focus

Submit a table outlining the population(s) of focus within the identified geographic area of focus using quantitative data.

4. Memoranda of Agreement (MOAs) and/or Letters of Commitment (LOCs)

If available at the time of submission, signed MOAs or signed LOCs may be submitted for each partner (or one signed MOA with all partners). MOAs and LOCs should include a description of the specific roles, responsibilities, resources, and contributions of partner(s) to the project.

Signed LOCs must detail the specific role and resources that will be provided, or activities that will be undertaken, in support of the applicant. The organization's expertise, experience, and access to the targeted population(s) should also be described in the LOC. Fully-executed MOAs may be required within the first 30 days following the start of the project period of any award made under this announcement.

MOAs and LOCs are not the same as letters of support. Letters of support are letters that are general in nature that speak to the writer's belief in the capability of an applicant to accomplish a goal/task. Letters of support also may indicate an intent or interest to work together in the future, but they lack specificity. You should NOT provide letters of support. Letters of support will not be considered during the review.

5. Organizational Chart

Include an organizational chart that reflects the management structure for the project and demonstrates where the project resides within the greater organization.

6. Curriculum Vitae/Résumés/Biosketches for Key Project Personnel

Submit with your application curriculum vitae, résumés, or biosketches of the Project Director/Principal Investigator, Evaluator, and others identified as essential in the proposal. Key Personnel includes those individuals in roles who will oversee the technical, professional, managerial, and essential support functions and/or assume responsibility for assuring the validity and quality of your organization's project. Do not include curriculum vitae, résumés, or biosketches for individuals who provide routine administrative support to the project as part of their broader support of the organization. You should use full names (first, middle, last) on these documents to distinguish them for verification in the System for Award Management exclusion records. You should use the formatting common to those documents. (See https://grants.nih.gov/grants/forms/biosketch.htm for templates and sample biographical sketches.)

7. References Cited

Include your references cited in your project narrative. You may use any standard format that you choose as long as it will clearly lead the reader to your source of information or data.

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

Your organization must register online in the System for Award Management (SAM). Grants.gov will reject submissions from applicants with nonexistent or expired SAM Registrations. You will find instructions on the Grants.Gov web site as part of the organization registration process at https://www.grants.gov/web/grants/applicants/organization-registration.html.

To register your organization, you will need a unique entity identifier (UEI). On April 4, 2022, the federal government completed its transition to the twelve-digit UEI(SAM) number as the required UEI for registration in SAM.gov.

You may begin the registration process, including receiving your UEI(SAM) at https://sam.gov/content/entity-registration. An Entity Registration Checklist is available at https://www.fsd.gov/gsafsd_sp/sys_attachment.do?sys_id=d6d6b5f31b120dd0cc45ea04bc4bcb81. You may register in SAM as either an entity applying for Federal Assistance Awards Only (e.g., grants and cooperative agreements) or All Awards (including procurement awards).

The Entity Registration Checklist contains a list of representations and certifications that must be certified by the organization as part of the SAM registration process annually. This list is reproduced in Section I.4. In accordance with the federal government's efforts to reduce reporting burden for recipients, we have transitioned to the common certification and representation requirements within SAM and no longer require SF-424B. By submitting your application to this NOFO, your authorized representative also certifies to these representations and certifications by signing Box 21 of SF-424A

Whether you are registering a new entity or renewing your registration, you must submit a notarized letter formally appointing an Entity Administrator to SAM.gov. For detailed instructions on the content of the letter and process for domestic entities see: https://www.fsd.gov/gsafsd_sp?id=kb_article_view&sysparm_article=KB0016652&sys_kb_id=f228607a1b2e8d54937fa64ce54bcbdb&spa=1.

You should allow a minimum of five days to complete an initial SAM registration. Allow up to 10 business days after you submit your registration for it to be active in SAM. This timeframe may be longer if SAM flags the information you provide for manual validation. You will receive an email alerting you when your registration is active.

You must renew your SAM registration each year. Organizations registered to apply for Federal awards through http://www.grants.gov will need to renew their registration in SAM. If you are successful and receive an award, you must maintain an active SAM registration with current information at all times during which your organization has an active award or an application or plan under consideration by an HHS agency.

You should make sure your SAM registration information is accurate, especially your organization's legal name and physical address including your ZIP+4. Should you successfully compete and receive an award, your organization's legal name and physical address must be included on a Notice of Award as it appears in SAM registration.

For instructions on updating information in your SAM registration see https://www.fsd.gov/sys_attachment.do?sys_id=d08b64ab1b4434109ac5ddb6bc4bcbbc.

It may take 24 hours or more for SAM updates to take effect in Grants.gov, so if you plan to apply for this funding opportunity or think you might apply, you should ensure your organization's registration is active in SAM well before the application deadline and will be active through the competitive review period.

HHS/OASH cannot make an award until you have complied with these requirements. In accordance with 2 C.F.R. § 25.205, at the time an award is ready to be made, if you have not complied with these requirements, HHS/OASH:

- May determine that you are not qualified to receive an award; and
- May use that determination as a basis for making an award to another applicant.

Should you successfully compete and receive an award, all first-tier sub-award recipients must have a UEI number at the time you, the recipient, make a sub-award to them.

5. Submission Dates and Times

You must submit your application for this funding opportunity by **the date and time indicated below.** Your submission time will be determined by the date and time stamp provided by Grants.gov when you **complete** your submission.

If you fail to submit your application by the due date and time, we will not review it, and it will receive no further consideration. You are strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date. Do not wait until the last day in the event you encounter technical difficulties, either on your end or with https://grants.gov. Grants.gov can take up to 48 hours to notify you of a successful or rejected submission. You are better off having a less-than-perfect application successfully submitted and under consideration than no application.

If your submission fails due to a system problem with Grants.gov, we may consider your application if you provide verification from Grants.gov indicating system problems existed at the time of your submission **and that time was before the submission deadline**. A "system problem" does not include known issues for which Grants.gov has posted instructions regarding how to successfully submit an application such as compatible Adobe versions or file naming conventions. **As the applicant, it is your responsibility to review all instructions available on Grants.gov regarding successfully submitting an application.**

a. Application Deadline

August 01, 2023
Your application is due by 6:00 PM Eastern Time

You must submit electronically via Grants.gov unless you obtain a written exemption from this requirement 2 business days in advance of the deadline from the Director, Grants and Acquisitions Management (GAM) Division, Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services (HHS). To obtain an exemption, you must request one via email from GAM, and provide details as to why you are technologically unable to submit electronically through Grants.gov. Your request should be submitted at least 4

business days prior to the application deadline to ensure your request can be considered prior to 2 business days in advance of the deadline.

If you request an exemption, include the following in your e-mail request: the HHS/OASH announcement number; your organization's UEI number; your organization's name, address and telephone number; the name and telephone number of your Authorizing Official; the Grants.gov Tracking Number (e.g., GRANT####) assigned to your submission; and a copy of the "Rejected with Errors" notification from Grants.gov. Send the request with supporting documentation to OASH_Grants@hhs.gov.

Failure to have an active System for Account Management (SAM) registration prior to the application due date will not be grounds for receiving an exemption to the electronic submission requirement. Failure to follow Grants.gov instructions to ensure software compatibility will not be grounds for receiving an exemption to the electronic submission requirement.

GAM will only accept applications via alternate methods (hardcopy paper via U.S. mail or other provider or PDF via email) from applicants obtaining prior written approval. If you receive an exemption, you must still submit your application by the deadline. Only applications submitted through the Grants.gov portal or alternate format (hardcopy paper via U.S. mail or other service or PDF via email) with an approved written exemption will be accepted. *See* Section D.8 ("Other Submission Requirements") for information on application submission mechanisms.

This announcement is subject to Executive Order 12372. The State Single Point of Contact (SPOC) has 60 days from the application due date to submit any comments. For more information on the SPOC see section F.6 Intergovernmental Review. See Section D.6.

To ensure adequate time to submit your application successfully, OASH recommends that you register as early as possible in Grants.gov because the registration process can take up to one month. You must register an authorizing official for your organization. OASH does not determine your organization's authorizing official; your organization makes that designation. For information on registering for Grants.gov, refer to https://grants.gov or contact the Grants.gov Contact Center 24 hours a day, 7 days a week (excluding Federal holidays) at 1-800-518-4726 or support@grants.gov.

Your organization is strongly encouraged to register multiple authorized organization representatives in Grants.gov to ensure someone is available to submit your application.

b. Technical Assistance

We will provide a technical assistance webinar for potential applicants on June 27, 2023, at 4:30 PM Eastern. Login details will be posted at www.minorityhealth.hhs.gov.

We recommend you review the entire announcement promptly so you can have any questions answered well in advance of the application due date. We also recommend you subscribe to this announcement in Grants.gov so you receive any amendments, question and answer documents, or other updates.

6. Intergovernmental Review

Applications under this announcement are subject to the requirements of Executive Order 12372, ‘‘Intergovernmental Review of Federal Programs,’’ as implemented by 45 C.F.R. part 100, ‘‘Intergovernmental Review of Department of Health and Human Services Programs and Activities.’’ As soon as possible, you should discuss the project with the State Single Point of Contact (SPOC) for the State in which your organization is located. The current listing of the SPOCs is available at https://www.whitehouse.gov/wp-content/uploads/2020/04/SPOC-4-13-20.pdf.

The SPOC should forward any comments to the Department of Health and Human Services 1101 Wootton Parkway, Plaza Level, Rockville, MD 20852. The SPOC has 60 days from the due date listed in this announcement to submit any comments. For further information, contact the HHS/OASH Grants and Acquisitions Management Division at 240–453–8822.

7. Funding Restrictions

Direct and Indirect Costs proposed and, if successful, charged to the HHS/OASH award must meet the cost requirements of 45 C.F.R. part 75 “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards,” Subpart E—Cost Principles. These requirements apply to you, the applicant, and any subrecipients. You should thoroughly review these regulations before developing your proposed budget.

Indirect costs may be included per 45 C.F.R. § 75.414. See Section D.3.b Budget Narrative for more information. To obtain a negotiated indirect cost rate with the Federal Government you may contact the U.S. Department of Health and Human Services Cost Allocation Services (CAS) regional office that is applicable to your State. CAS regional contact information is available at https://rates.psc.gov/fms/dca/map1.html.

a. Pre-Award Costs

Pre-award costs are NOT allowed. Pre-award costs (per 45 C.F.R. § 75.458) are those incurred prior to the effective date of the Federal award directly pursuant to the negotiation and in anticipation of the Federal award where such costs are necessary for efficient and timely performance of the scope of work.

b. Salary Rate Limitation

Each year’s appropriations act limits the salary rate that we may award and you may charge to HHS/OASH grants and cooperative agreements. You should not budget award funds to pay the salary of an individual at a rate in excess of Federal Executive Pay Scale Executive Level II. As of January 2023, the Executive Level II salary is $212,100. This amount reflects an individual’s base salary exclusive of fringe benefits and any income that an individual working on the award project may be permitted to earn outside of the duties to the applicant organization. This salary rate limitation also applies to subawards/subcontracts under an HHS/OASH award. An example

of the application of this limitation for an individual devoting 50% of their time to this award is broken down below:

Individual's *actual* base full-time salary: $350,000 50% of time devoted to project, i.e., 0.5 FTE	
Direct salary ($350,000 x 0.5)	$175,000
Fringe (25% of salary)	$43,750
Total	$218,750
Amount that may be claimed on the application budget due to the legislative salary rate limitation: Individual's base full-time salary *adjusted* to Executive Level II: $212,100 with 50% of time devoted to the project	
Direct salary ($212,100 x 0.5)	$106,050
Fringe (25% of salary)	$26,512.50
Total amount allowed	$132,562.50

Appropriate salary rate limits will apply as required by law.

8. Other Submission Requirements

a. **Electronic Submission**

HHS/OASHrequires that all applications be submitted electronically via the Grants.gov portal unless an exemption has been granted. If you submit an application via any other means of electronic communication, including facsimile or electronic mail, it *will not* be accepted for review unless you receive an exemption as described in the DATES section of this announcement.

You may access the Grants.gov website portal at https://grants.gov.
Applications, excluding required standard forms, must be submitted as three (3) files (see acceptable file types below). One file must contain the entire Project Narrative, another the entire Budget Narrative including supporting documentation described in the Budget Narrative content section; and the third file must contain all documents in the Appendices. Any additional files submitted as part of the Grants.gov application will not be accepted for processing and will be excluded from the application during the review process.

Any files uploaded or attached to the Grants.gov application must be Adobe PDF, Microsoft Word, or image formats (JPG, GIF, TIFF, or BMP only) and must contain a valid file format extension in the filename. **We will not accept Microsoft Excel files.**

In addition, the use of compressed file formats such as ZIP, RAR, or Adobe Portfolio will not be accepted. We will not contact you for resubmission of uncompressed versions of files. Compressed files in the application will not be forwarded to the independent merit review panel for consideration.

We strongly recommend that electronic applications be uploaded as Adobe PDF. If you convert to PDF prior to submission, you may prevent any unintentional formatting that might occur with submission of an editable document. Although Grants.gov allows you to attach any file format as part of your application, we restrict this practice and only accept the file formats identified above for compatibility with our other systems. Any file submitted as part of the Grants.gov application that is not in a file format listed above will not be accepted for processing and will be excluded from the application during the review process.

Any file submitted as part of the Grants.gov application that contains password protection will not be accepted for processing and will be excluded from the application during the review process. We will not contact you for passwords or resubmission of unprotected files. Unprotected information in the application will be forwarded for consideration but password protected portions will not. You should avoid submitting personally identifiable information such as personal contact information on résumés.

You must submit your application in a format that can easily be copied and read by reviewers. We do not recommend that you submit scanned copies through Grants.gov unless you confirm the clarity of the documents. Pages cannot be reduced resulting in multiple pages on a single sheet to avoid exceeding the page limitation. If you submit documents that do not conform to these instructions, we will exclude them from your application during the review process.

b. **Important grants.gov Information**

You may access the electronic application for this program on https://grants.gov. You must search the downloadable application page by the Opportunity Number or Assistance Listing (formerly CFDA) number, both of which can be found on page 1 of this funding opportunity announcement.

To ensure successful submission of your application, you should carefully follow the step-by-step instructions provided at http://www.grants.gov/web/grants/applicants/apply-for-grants.html . These instructions are kept up-to-date and also provide links to Frequently Asked Questions and other troubleshooting information. **You are responsible for reviewing all Grants.gov submission requirements on the Grants.gov site.**

You should contact Grants.gov with any questions or concerns regarding the electronic application process conducted through Grants.gov. See Section G.3 for contact information.

See Section D.4 for requirements related to UEI numbers and SAM registration.

c. Program-Specific Requirements

There are no program specific requirements.

E. APPLICATION REVIEW INFORMATION

1. Criteria

Federal staff and an independent review panel will assess all eligible applications according to the following criteria. Disqualified applications will not be reviewed against these criteria.

a. Significance of the Project (10 points)

The application makes a well-supported case with quantitative data that it will benefit the field, targeted population, and society (i.e., significance of the project) by addressing the contributing factors to the barriers to increasing participation in lupus clinical trials. The application provides a rationale for the level of public-private partnerships and community partnerships to support and sustain project activities for lasting impact.

b. Goals, Objectives and Outcomes (15 Points)

The application demonstrates a strong, clear alignment of goals, objectives, and measurable outcomes for the selected intervention. The objectives are specific, measurable, achievable, realistic, time-bound, inclusive, and equitable (SMARTIE) and quantified, and include baseline data and quantifiable time-frames for achievement within the anticipated period of performance. The application clearly describes the expected measurable outcome(s) that would result from the proposed project, including public, private, and community partnerships. Intervention objectives rationally related to the overall goals of the project rather than project activities. Goals are ambitious and achievable in the period of performance. Expected outcome(s) are reasonably measured as proposed and will demonstrate the impact of the intervention.

c. Project Plan (25 points)

The project plan, including the work plan and activities described, will reasonably assist in the achievement of the stated project goals and objectives, including increasing racial and ethnic minority participation in lupus-related clinical trials. The lupus intervention selected (previously OMH-funded or other) for this project is clearly suitable to address any identified evidence gaps, needs, and the proposed project activities.

The approach and rationale for recruiting, enrolling, and retaining intervention participants is well-developed and likely to increase the number of participants, recruited, screened, and enrolled into lupus clinical trials. The approach anticipates barriers to minority participation in lupus clinical trials and accounts for them. The proposed approach for developing public-private and community partnerships and related activities will support the success of the project.

The proposed intervention is culturally and linguistically appropriate for the population of focus and applies the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (National CLAS Standards).

The approach to use data collected over the course of the project to support quality improvement is sound, including ensuring the project is implemented in a culturally appropriate manner over the full period of performance.

d. Organizational Capacity (20 points)

The application shows an organization capable of carrying out the activities described in the work plan based on relevant experience, including working on clinical trials with racial and ethnic minority populations; providing outreach and education to racial and ethnic minority populations; clinical trial outreach to increase enrollment and retention; evaluation of outreach and training programs. Where appropriate, the proposed intervention engages CHWs and other patient advocates in outreach, education and training related to recruitment and participation in clinical trials. The organizations current and planned engagement with community and partnering organizations is relevant and beneficial to the proposed project's anticipated success.

The application demonstrates a readiness to implement the project and achieve measurable outcomes within the period of performance, including all key personnel and partners, with necessary expertise. Individuals/organizations responsible for evaluation activities have the necessary qualifications and degree of independence.

e. Evaluation Plan (20 Points)

The evaluation plan is a feasible and rigorous evaluation approach for effectively demonstrating the impact of the project on the population of focus and on disparities in clinical trial enrollment and whether project activities resulted in the intended outcomes while adequately controlling for threats to validity.

The data identified for collection to be used to ensure the project activities are achieving their intended objectives and outcomes is reasonably appropriate and obtainable, including baseline, interim, and post-intervention process and outcome data. Any potential challenges to data collection are described with reasonable approaches to address them. The project’s logic model, including how the inputs, processes, outputs, and outcomes will be measured, is rational and well-supported. Any involvement of partners in the evaluation activities is appropriate and beneficial to the overall evaluation.

f. Dissemination Plan (10 Points)

The approach described an adequate method to disseminate the results and findings of the intervention and its impact including innovative approaches to reach the population served, the general public, and other parties who might be interested in using the results of the project. The plan enables timely dissemination in easily understandable formats to the intended audience(s).

2. Review and Selection Process

An independent review panel will evaluate applications that are not disqualified and meet the responsiveness criteria (Section C.3). These reviewers are experts in their fields, and are drawn

from academic institutions, non-profit organizations, state and local government, and Federal government agencies. Based on the Application Review Criteria as outlined under Section E.1, the reviewers will comment on and rate the applications, focusing their comments and ratings on the identified criteria. In addition to the independent review panel, Federal staff will review each application for programmatic, budgetary, and grants management compliance.

The Deputy Assistant Secretary for Minority Health will provide recommendations for funding to the Grants Management Officer to conduct risk analysis. No award decision is final until a Notice of Award is issued by the Grants Management Officer.

In providing these recommendations the Deputy Assistant Secretary for Minority Health will take into consideration the following additional factors(s):

- Equitable geographic distribution

3. Review of Risk Posed by Applicant

GAM will evaluate, in accordance with 45 C.F.R. § 75.205, each application recommended for funding by the program official indicated in Review and Selection Process for risks before issuing an award. This evaluation may incorporate results of the evaluation of eligibility or the quality of an application. If we determine that a Federal award will be made, special conditions that correspond to the degree of risk assessed will be applied to the Federal award. Such conditions may include additional programmatic or financial reporting or releasing funds on a reimbursable rather than cash advance basis. We will use a risk-based approach and may consider any items such as the following*:*

a. Your financial stability;

b. Quality of management systems and ability to meet the management standards prescribed in 45 C.F.R. part 75;

c. History of performance. Your record in managing Federal awards, if you are a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

d. Reports and findings from audits performed; and

e. Your ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

Prior to making a Federal award with a total Federal share greater than the simplified acquisition threshold (currently $250,000), we are required to review and consider any information about you that is in the designated integrity and performance system accessible through the System for Award Management (SAM) (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). You may, at your option, review information in SAM and comment on any information about yourself that a Federal awarding agency previously entered

and is currently available through SAM. We will consider any comments by you, in addition to the other information in the designated system, in making a judgment about your integrity, business ethics, and record of performance under Federal awards when completing the review of risk.

If we do not make an award to you because we determine your organization does not meet either or both of the minimum qualification standards as described in 45 C.F.R. § 75.205(a)(2), we must report that determination to FAPIIS, if certain conditions apply. At a minimum, the information in the system if you are a prior Federal award recipient must "demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics." 45 C.F.R. § 75.205(a)(2); see also 45 C.F.R. §75.212 for additional information.

4. Final Award Decisions, Anticipated Announcement, and Federal Award Dates

Upon completion of risk analysis and concurrence of the Grants Management Officer, OASH will issue Notices of Award. No award decision is final until a Notice of Award is issued. All award decisions, including the level of funding if an award is made, are final and you may not appeal.

OASH seeks to award funds as much in advance of the anticipated project start date shown in Section B "Federal Award Information," as practicable, with a goal of 10-15 days. Note this is an estimated start date and award announcements may be made at a later date and with a later period of performance start date.

F. FEDERAL AWARD ADMINISTRATION INFORMATION

1. Federal Award Notices

We do not release information about individual applications during the review process. If you would like to track your application, please see instructions at https://www.grants.gov/web/grants/applicants/track-my-application.html.

The official document notifying you that an application has been approved for funding is the Notice of Award (NOA), approved by a Grants Management Officer within GAM. If you are successful, you will receive this document via a system notification from our grants management system (Grant Solutions) and/or via e-mail. This document notifies the successful recipient of the amount awarded, the purposes of the award, the anticipated length of the period of performance, terms and conditions of the award, and the amount of funding to be contributed by the recipient to project costs, if applicable.

If you receive an NOA, we strongly encourage you to read the entire document to ensure your organization's information is correct and that you understand all terms and conditions. You should pay specific attention to the terms and conditions, as some may require a time-limited

response. The NOA will also identify the Grants Management Specialist and Program Project Officer assigned to the award for assistance and monitoring.

If you are unsuccessful or deemed ineligible according to the disqualification criteria, you will be notified by OASH by email and/or letter. If your application was reviewed by the independent review panel, you may receive summary comments pertaining to the application resulting from the review process. We do not customarily release application scores.

You may receive a letter indicating that your application was "approved but unfunded." This does not mean you will receive an award or funding. Applications designated "approved but unfunded" are typically kept active for up to one year. During that time, the program office may consider an application with this status for award under this NOFO should funds become available. The status "approved but unfunded" does not guarantee that we will fund your project. We will not transfer an "approved but unfunded" application for consideration under a new NOFO. You would need to resubmit your application, with any updated material, for consideration under that new NOFO.

2. Administrative and National Policy Requirements

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 C.F.R. part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

In addition, your organization must comply with all terms and conditions outlined in the Notice of Award, the U.S. Department of Health and Human Services (HHS) Grants Policy Statement (GPS), requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable, as well as any requirements or limitations in any applicable appropriations acts. The current HHS GPS is available at https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf. Please note HHS plans to revise the HHS GPS to reflect changes to the regulations; 45 C.F.R. parts 74 and 92 which have been superseded by 45 C.F.R. part 75.

You may only use award funds to support activities outlined in the approved project plan. If your application is funded, your organization will be responsible for the overall management of activities within the scope of the approved project plan. Please consult the HHS GPS Section II and 45 C.F.R. § 75.308 for aspects of your funded project that will require prior approval from the Grants Management Officer for any changes. Modifications to your approved project that will require prior approval include, but are not limited to: a change in the scope or the objective(s) of the project or program (even if there is no associated budget revision, such as reduction in services, closing of service or program site(s)); significant budget revisions, including changes in the approved cost-sharing or matching; a change in a key person specified in your application; reduction in time devoted to the project by the approved project director or principal investigator, either as percentage of full-time equivalent of 25% or more or absence for

3 months or more; or the subawarding, transferring or contracting out of any work that was not described in the approved proposal.

The termination provisions in 2 CFR §§ 200.340(a)(1)-(4) are the termination provisions that are applicable to awards issued under this NOFO. No additional termination provisions apply unless otherwise noted under Section F.3 Program Specific Terms and Conditions.

3. Program Specific Terms and Conditions

a. Paperwork Reduction Act Clearance Packages

Any collection of information you conduct as defined in 5 C.F.R. § 1320.3(c) may require OMB clearance under the Paperwork Reduction Act if it is a requirement of your award to collect that information. You will be responsible for preparing the clearance package necessary to obtain Paperwork Reduction Act clearance and submitting it to the project officer. The project officer will assist in the submission of the package to OMB and notify you when the approval has been received or request additional information.

b. Disparity Impact Statement (DIS)

Successful recipients are required to develop a disparity impact statement (DIS) using local data and input to identify populations at highest risk for health, social, economic, or other disparities such as low health literacy. Recipients may choose to use the Centers for Disease Control (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR) Social Vulnerability Index (SVI) (https://www.atsdr.cdc.gov/placeandhealth/svi/index.html), or other local data tools, in developing disparity impact statements.

The DIS 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.
Project activities must comply with the non-discrimination requirements described in Section F.6.

Below are available HHS resources:

- OMH Disparity Impact Strategy (https://www.minorityhealth.hhs.gov/omh/content.aspx?ID=22540)
- CMS.gov: Quality Improvement & Interventions: Disparity Impact Statement (https://www.cms.gov/About-CMS/Agency-Information/OMH/resource-center/hcps-and-researchers/quality-improvements-and-interventions)
- SAMHSA.gov: Disparity Impact Statement (https://www.samhsa.gov/grants/grants-management/disparity-impact-statement)

Additional information and links to resources are available in Section I.4.

4. Closeout of Award

Upon expiration of your period of performance, you must submit within 120 days all necessary documentation to closeout your award. If we do not receive acceptable final performance, financial, and/or property reports in a timely fashion within the closeout period, and we determine that closeout cannot be completed with your cooperation or that of the PD/PI, we must complete a unilateral closeout with the information available to us. (See F.16 Reporting below for closeout reporting requirements.)

If you do not submit all reports within one year of the period of performance end date, we must report your material failure to comply with the terms and conditions of the award with the OMB-designated integrity and performance system (currently FAPIIS). As a result, we may also determine that enforcement actions are necessary, including on another existing or future award, such as withholding support or a high-risk designation.

5. Lobbying Prohibitions

You shall not use any funds from an award made under this announcement for other than normal and recognized executive legislative relationships. You shall not use funds for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

You shall not use any funds from an award made under this announcement to pay the salary or expenses of any employee or subrecipient, or agent acting for you, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

The above prohibitions include any activity to advocate or promote any proposed, pending, or future Federal, State, or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

6. Non-Discrimination Requirements

Should you successfully compete for an award, as a recipient of federal financial assistance (FFA) from HHS you 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. 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 on the basis of 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/forproviders/provider-obligations/index.html and https://www.hhs.gov/civil-rights/forindividuals/nondiscrimination/index.html.

- For guidance on meeting the 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 the specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, 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 program 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.

Contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html or call 1-800-368-1019 or TDD 1-800-537-7697.

The *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care* (National CLAS Standards), 78 Fed. Reg. 58539, 58543 (HHS Office of Minority Health, 2013, https://www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23164.pdf, provides a practical framework for applicants to provide quality health care and services to culturally and linguistically diverse communities, including persons with limited English proficiency. For further guidance on providing culturally and linguistically appropriate services, you should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

7. Smoke- and Tobacco-free Workplace

The HHS/OASH strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. This is consistent with the HHS/OASH mission to protect and advance the physical and mental health of the American people.

8. Acknowledgement of Funding

Each year's annual appropriation requires that when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all organizations receiving Federal funds, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state— (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

You must also acknowledge Federal support in any publication you develop using funds awarded under this program, with language such as:

> This [project/publication/program/website, etc.] was supported by [Award Number] issued by the Office of the Assistant Secretary for Health of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $XX with 100 percent funded by [PROGRAM OFFICE].

Recipients must also include a disclaimer stating the following

> The contents are solely the responsibility of the author(s) and do not necessarily represent the official views of, nor an endorsement by, [PROGRAM OFFICE], OASH, HHS, or the U.S. Government. For more information, please visit [PROGRAM OFFICE website, if available].

9. HHS Rights to Materials and Data

All publications you develop or purchase with funds awarded under this announcement must be consistent with the requirements of the program. You own the copyright for materials that you develop under this award, and pursuant to 45 C.F.R. § 75.322(b), HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for Federal purposes, and to authorize others to do so. In addition, pursuant to 45 C.F.R. § 75.322(d), the Federal government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

10. Trafficking in Persons

Awards issued under this NOFO are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. § 7104) (See https://www.govinfo.gov/content/pkg/USCODE-2010-title22/html/USCODE-2010-title22-chap78-sec7104.htm).

11. Efficient Spending

This award may also be subject to the HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing and Publications available at https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/.

12. Whistleblower Protection

If you receive an award, you will be subject to a term and condition that applies the terms of 48 C.F.R. § 3.908 to the award, and requires that you inform your employees in writing of employee whistleblower rights and protections under 41 U.S.C. § 4712 in the predominant native language of the workforce.

13. Health Information Technology (IT) Interoperability

Health information technology is defined in Section 3000 of the Public Health Service Act (42 U.S.C. § 300jj). HHS has substantially adopted and codified that definition at 45 C.F.R. § 170.102. The regulation defines health information technology as hardware, software, integrated technologies or related licenses, IP, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.

If you receive an award under this NOFO that involves:

a. implementing, acquiring, or upgrading health IT for activities, you are required to utilize health IT that meets standards and implementation specifications adopted in 45 CFR Part 170, Subpart B, if such standards and implementation specifications can support the activity.
b. implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Section 4101, 4102, and 4201 of the HITECH Act , you are required to utilize health IT certified under the Office of the HHS Office of the National Coordinator for Health Information technology (ONC) Health IT Certification Program, if certified technology can support the activity. See https://www.healthit.gov/topic/certification-ehrs/certification-health-it.

If standards and implementation specifications adopted in 45 CFR Part 170, Subpart B cannot support the activity, recipients and subrecipients are encouraged to utilize health IT that meets non-proprietary standards and implementation specifications developed by consensus-based standards development organizations. This may include standards identified in the ONC Interoperability Standards Advisory, available at https://www.healthit.gov/isa/.

14. Prohibition on certain telecommunications and video surveillance services or equipment.

As described in 2 C.F.R. 200.216, recipients and subrecipients are prohibited from obligating or spending grant funds (to include direct and indirect expenditures as well as cost share and program) to:

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

i. For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).
ii. Telecommunications or video surveillance services provided by such entities or using such equipment.
iii. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

15. Human Subjects Protection

Federal regulations (45 C.F.R part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in 45 C.F.R. part 46. Additional information is available at https://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

Recipients that plan to engage in research involving human subjects are encouraged to provide information regarding participation in research in their recruitment efforts and provide a link to https://www.hhs.gov/about-research-participation.

OASH may require, as part of any award, the submission of all IRB approvals within 5 days of the IRB granting the approval and before any work requiring IRB approval begins.

16. Research Integrity

An applicant for or recipient of PHS support for biomedical or behavioral research, research training or activities related to that research or research training must comply with 42 C.F.R. part 93, including have written policies and procedures for addressing allegations of research misconduct that meet the requirements of part 93, file an Assurance of Compliance with the Office of Research Integrity (ORI), and take all reasonable and practical steps to foster research integrity consistent with 42 C.F.R. § 93.300. The assurance must state that the recipient (1) has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and (2) complies with its own policies and procedures and the requirements of part 93. More information is available at https://ori.hhs.gov/assurance-program.

17. Reporting

a. Performance Project Reports (PPR)

You must submit periodic performance project reports on a quarterly basis. Your performance reports must address content required by 45 C.F.R. § 75.342(b)(2). The awarding program office may provide additional guidance on the content of the progress report. You must submit your performance reports by the due date indicated in the terms and conditions of your award via upload to our grants management system (GrantSolutions.gov).

You will also be required to submit a final performance report covering the entire period of performance 120 after the end of the period of performance. The awarding program office may provide additional guidance on the content of the progress report. You must submit the final report by upload to our grants management system (GrantSolutions.gov).

b. Performance Measures

Performance is assessed relative to meeting the goals, objectives, and outcomes in the approved, funded project as described in the approved work plan and other supporting documents.

At the end of each reporting period, you should be able to describe the performance in terms of:

1. Accomplishments and progress toward program purpose/strategies/interventions and disparity impact statement.
2. Status of the project's staffing situation.
3. The role and activities of each partnering organization.
4. Accomplishments, current or anticipated problems, changes and progress on the evaluation plan.

c. Financial Reports

You will be required to submit quarterly Federal Financial Reports (FFR) (SF-425). Your specific reporting schedule will be issued as a condition of award. You will also be required to submit a final FFR covering the entire period of performance 120 days after the end of the period of performance. You must submit FFRs via HHS Payment Management System (PMS) (https://pms.psc.gov).

Once submitted and accepted, your financial reports will be available in GrantSolutions, which is our grant management system.

d. Audits

If your organization expends $750,000 or greater in federal funds, it must undergo an independent audit in accordance with 45 C.F.R. 75, subpart F.

e. Non-competing Continuation Applications and Awards

Each year of the approved period of performance, you will be required to submit a noncompeting application which includes a progress report for the current budget year, and work plan, budget and budget justification for the upcoming year. Specific guidance will be provided via Grant Solutions well in advance of the application due date. OASH will award continuation funding based on availability of funds, satisfactory progress of the project, grants management compliance, including timely reporting, and continued best interests of the government. Progress is assessed relative to meeting the goals, objectives, and outcomes in the approved, funded project as described in the approved work plan and other supporting documents.

For the optional competitive additional year of funding for transition to sustainability, application guidance and review criteria will be provided during the third year of the project.

Failure to provide final progress or financial reports on other awards from HHS may affect continuation funding.

f. **FFATA and FSRS Reporting**

The Federal Financial Accountability and Transparency Act (FFATA) requires data entry at the FFATA Subaward Reporting System (https://www.FSRS.gov) for all sub-awards and sub-contracts issued for $30,000 or more as well as addressing executive compensation for both recipient and sub-award organizations.

g. **Reporting of Matters Relating to Recipient Integrity and Performance**

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of this Federal award, then you must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and

Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph A.2 of Appendix XII to 45 C.F.R. part 75—Award Term and Condition for Recipient Integrity and Performance Matters. This is a statutory requirement (41 U.S.C. § 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. For more information about this reporting requirement related to recipient integrity and performance matters, see Appendix XII to 45 C.F.R. part 75.

h. **Other Required Notifications**

Before you enter into a covered transaction at the primary tier, in accordance with 2 C.F.R. § 180.335, you as the participant must notify OASH, if you know that you or any of the principals for that covered transaction:

- Are presently excluded or disqualified;
- Have been convicted within the preceding three years of any of the offenses listed in 2 C.F.R. § 180.800(a) or had a civil judgment rendered against you for one of those offenses within that time period;
- Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses listed in 2 C.F.R. § 180.800(a); or
- Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years for cause or default.

At any time after you enter into a covered transaction, in accordance with 2 C.F.R. § 180.350, you must give immediate written notice to OASH if you learn either that—

- You failed to disclose information earlier, as required by 2 C.F.R. § 180.335; or
- Due to changed circumstances, you or any of the principals for the transaction now meet any of the criteria in 2 C.F.R. § 180.335.

G. CONTACTS

1. Administrative and Budgetary Requirements

For information related to administrative and budgetary requirements, contact the HHS/OASH grants management specialist listed below.

Duane Barlow
OASH Grants and Acquisitions Management
1101 Wootton Parkway, Plaza Level
Rockville, MD 20852
Phone: 240-453-8822

Email: duane.barlow@hhs.gov

2. Program Requirements

For information on program requirements, please contact the program office representative listed below.

Paul Rodriguez
Office of Minority Health
1101 Wootton Parkway, Rockville, MD 20852
Phone: 240-453-2882
Email: paul.rodriguez@hhs.gov

3. Electronic Submission Requirements

For information or assistance on submitting your application electronically via Grants.gov, please contact Grants.gov directly. Assistance is available 24 hours a day, 7 days per week.

GRANTS.GOV Applicant Support

Website: https://www.grants.gov

Phone: 1-800-518-4726

Email: support@grants.gov

H. OTHER INFORMATION

1. Awards under this Announcement

We are not obligated to make any Federal award as a result of this announcement. If awards are made, they may be issued for periods shorter than indicated. Only the grants officer can bind the Federal government to the expenditure of funds.

If you receive communications to negotiate an award or request additional or clarifying information, this does not mean you will receive an award; it only means that your application is still under consideration.

2. Application Elements

The below is a summary listing of all the application elements required for this funding opportunity.

Application for Federal Assistance (SF-424)

Budget Information for Non-construction Programs (SF-424A)

Disclosure of Lobbying Activities (SF-LLL)

Project Abstract Summary

Project Narrative – Submit all Project Narrative content as a single acceptable file, specified above.

Budget Narrative – Submit all Budget Narrative content as a single acceptable file, specified above.

Appendices – Submit all appendix content as a single acceptable file, specified above **in the Attachments section of your Grants.gov application**.

- Work Plan
- Logic Model
- Project Population(s) of Focus
- Memoranda of Agreement (MOAs) and/or Letters of Commitment (LOCs)
- Organizational Chart
- Curriculum Vitae/Résumés/Biosketches for Key Project Personnel
- References Cited

I. SUPPLEMENTARY MATERIALS

1. Acronyms

CHW	Community Health Worker
DIS	Disparity Impact Statement
FAPIIS	Federal Awardee Performance and Integrity Information System
FFATA	Federal Financial Accountability and Transparency Act
FFR	Federal Financial Report (SF-425)
FSRS	FFATA Subaward Reporting System
GAM	Grants and Acquisitions Management Division
GMO	Grants Management Officer
GMS	Grants Management Specialist
GPS	Grants Policy Statement
HHS	Department of Health and Human Services
NOA	Notice of Award
NOFO	Notice of Funding Opportunity
OASH	Office of the Assistant Secretary for Health
OMB	Office of Management and Budget
PD/PI	Project Director/Principal Investigator
PHS	Public Health Service
PPR	Performance Project Report
SPOC	State Single Point of Contact

2. Considerations in Recipient Plans for Oversight of Federal Funds

(See also Section D.3.b.2)

To the maximum extent possible, a recipient organization should segregate responsibilities for receipt and custody of cash and other assets; maintaining accounting records on the assets; and authorizing transactions. In the case of payroll activities, the organization, where possible, should segregate the timekeeping, payroll preparation, payroll approval, and payment functions.

Questions for consideration in developing your plan may include:

- Do the written internal controls provide for the segregation of responsibilities to provide an adequate system of checks and balances?
- Are specific officials designated to approve payrolls and other major transactions
- Does the time and accounting system track effort by cost objective?
- Are time distribution records maintained for all employees when his/her effort cannot be specifically identified to a particular program cost objective?
- Do the procedures for cash receipts and disbursements include:
    - Receipts are promptly logged in, restrictively endorsed, and deposited in an insured bank account?
    - Bank statements are promptly reconciled to the accounting records, and are reconciled by someone other than the individuals handling cash, disbursements and maintaining accounting records?
    - All disbursements (except petty cash or EFT disbursements) are made by pre-numbered checks?
    - Supporting documents (e.g., purchase orders, Invoices, etc.) accompany checks submitted for signature and are marked "paid" or otherwise prominently noted after payments are made?

3. Financial Assistance General Certifications and Representations

When your organization completes its registration (new or renewal) in SAM.gov, your organization has attested to the accuracy of the below. Note that HHS awards are currently subject to 45 C.F.R. part 75. Where applicable the parallel citation to 45 C.F.R. part 75 is supplied in brackets following the 2 C.F.R. part 200 citation.

a. Has the legal authority to apply for federal assistance and the institutional, managerial and financial capability to ensure proper planning, management, and completion of any financial assistance project covered by this Certifications and Representations document (See 2 C.F.R. § 200.113 Mandatory disclosures [45 C.F.R. § 75.113], 2 C.F.R. § 200.214 Suspension and debarment [45 C.F.R. § 75.213], OMB Guidance A- 129, "Policies for Federal Credit Programs and Non-Tax Receivables");

b. Will give the awarding agency, the Comptroller General of the United States and, if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives (See 2 C.F.R. § 200.302 Financial Management [45 C.F.R. § 75.302] and 2 C.F.R. § 200.303 Internal controls [45 C.F.R. § 75.303]);

c. Will disclose in writing any potential conflict of interest to the federal awarding agency or pass through entity in accordance with applicable federal awarding agency policy (See 2 C.F.R. § 200.112 Conflict of interest [45 C.F.R. § 75.112]);

d. Will comply with all limitations imposed by annual appropriation acts;

e. Will comply with the U.S. Constitution, all federal laws, and relevant Executive guidance in promoting the freedom of speech and religious liberty in the administration of federally-funded programs (See 2 C.F.R. § 200.300 Statutory and national policy requirements [45 C.F.R. § 75.300] and 2 C.F.R. § 200.303 Internal controls [45 C.F.R. § 75.303]);

f. Will comply with all applicable requirements of all other federal laws, executive orders, regulations, and public policies governing financial assistance awards and any federal financial assistance project covered by this certification document, including but not limited to:

1. Trafficking Victims Protection Act (TVPA) of 2000, as amended, 22 U.S.C. § 7104(g);

2. Drug Free Workplace, 41 U.S.C. § 8103;

3. Protection from Reprisal of Disclosure of Certain Information, 41 U.S.C. § 4712;

4. National Environmental Policy Act of 1969, as amended, 42 U.S.C. § 4321 et seq;

5. Universal Identifier and System for Award Management, 2 C.F.R. part 2;

6. Reporting Subaward and Executive Compensation Information, 2 C.F.R. part 170;

7. OMB Guidelines to Agencies on Governmentwide Debarment and Suspension

(Non-procurement), 2 C.F.R. part 180;

8. Civil Actions for False Claims Act, 31 U.S.C. § 3730;

9. False Claims Act, 31 U.S.C. §3729, 18 U.S.C. §§ 287 and 1001;

10. Program Fraud and Civil Remedies Act, 31 U.S.C. § 3801 et seq;

11. Lobbying Disclosure Act of 1995, 2 U.S.C. § 1601 et seq;

12. Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d et seq;

13. Title VIII of the Civil Rights Act of 1968, 42 U.S.C. § 3601 et seq;

14. Title IX of the Education Amendments of 1972, as amended; 20 U.S.C. § 1681 et seq

15. Section 504 of the Rehabilitation Act of 1973, as amended; 29 U.S.C. § 794; and

16. Age Discrimination Act of 1975, as amended, 42 U. S.C. § 6101 et seq.

4. Disparity Impact Statements

Disparity impact statements are a part of a comprehensive data-driven approach for identifying and addressing health disparities to promote health equity for racial and ethnic minority populations. A DIS refers to the demographic, cultural, and linguistic data that identify the population(s) in which health disparities exist and the quality improvement plan designed to address the noted disparities.

The DIS will provide the measurement framework for ongoing monitoring and determining the impact of the project activities on outcomes and overarching goal of advancing health equity.

Agencies within the U.S. Department of Health and Human Services offer resources to support developing a Disparity Impact Statement, including the following:

- Building an Organizational Response to Health Disparities: Disparities Impact Statement (https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf)
- HDPulse — An Ecosystem of Minority Health and Health Disparities Resources (https://www.nimhd.nih.gov/resources/hd-pulse.html)

5. Existing OMH-funded Interventions

- American College of Rheumatology's Collaborative Initiatives, The Lupus Initiative® (TLI) - a multifaceted education program designed to reduce disparities and improve outcomes among people with lupus. https://thelupusinitiative.org/
- Northwestern University Lupus Conversations Learning Modules, https://www.lupus.northwestern.edu/education/omh.learning.html
- The Oklahoma Research Foundation, https://empower.crisalisllc.com/
- Lupus Foundation of America, https://www.lupus.org/for-researchers/improving-minority-participation-and-awareness-in-clinical-trials ; https://www.lupus.org/partnerships-andcollaborations/ increasing-minority-participation-and-awareness-in-clinical- trials
- New Jersey Chapter, American Academy of Pediatrics, https://njaap.org/programs/lupus/resources/

6. Clinical Trial Locator Resources

https://Clinicaltrials.gov

https://www.fda.gov/consumers/minority-health-and-health-equity/clinical-trial-diversity

https://www.nih.gov/health-information/nih-clinical-research-trials-you

About Lupus Trials - What is Lupus - Lupus Clinical Trials

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