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DEPARTMENT OF  
HEALTH AND HUMAN SERVICES  
OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

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

**Opportunity Number: MP-CPI-21-005**

**Application Due Date:**

**June 29, 2021 at 6:00 PM Eastern**

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# OVERVIEW

## FEDERAL AGENCY NAME

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 Competitive Grant

## FUNDING OPPORTUNITY NUMBER

MP-CPI-21-005

## ASSISTANCE LISTING NUMBER AND PROGRAM:

93.137 Community Program to Improve Minority Health

## DATES

*Application Deadline:* June 29, 2021 by 6:00 PM Eastern.

*Technical Assistance:* Webinar, May 5, 2021 at 3:00 PM Eastern.

## EXECUTIVE SUMMARY

The Office of Minority Health announces the availability of funds for Fiscal Year (FY) 2021 grants under the authority of 42 U.S.C. § 300u-6 (Section 1707 of the Public Health Service Act).

This notice solicits applications for projects for the National Lupus Outreach and Clinical Trial Education Program (Lupus Program).

The Lupus Program seeks to demonstrate the effectiveness of interventions for increasing minority participation in lupus-related clinical trials to help to reduce lupus-related health disparities experienced by racial and ethnic minority populations. Studies have indicated that

Blacks, Asians, Pacific Islanders, and Hispanics experience higher rates of diagnosis of system lupus erythematosus (SLE) and more severe symptoms and complications than whites. Projects will seek to develop public-private and community partnerships to support and/or sustain effective practices to increase racial and ethnic minority enrollment and retention in lupus clinical trials, and tailor existing outreach or education interventions that focus on health care providers/practitioners and/or racial and ethnic minority populations.

Clinical trials play a key role in identifying and developing new and better treatments for lupus. In the US, clinical trials for lupus have had limited success in recruiting minority participants. This is in line with the underrepresentation of racial and ethnic minority populations in clinical trials in general. OMH expects the Lupus Program to result in the identification of effective interventions that increase racial and ethnic minority enrollment and retention in lupus clinical trials.

Reducing and eliminating health disparities is a critical step toward promoting and achieving health equity. OMH expects awardees to address health disparities among racial and ethnic minority populations, to demonstrate the impact of those efforts on outcomes and the overarching goal of advancing health equity.

OMH anticipates the availability of \$2,000,000 to support up to six awards, ranging from \$300,000 to \$500,000 annually for a project period of up to two years.

HHS/OASH encourages 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 its application complies with all requirements and instructions.

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## FUNDING OPPORTUNITY DETAILS

### A. DATES

#### 1. Application Deadline

Your application is due June 29, 2021 by 6 p.m. Eastern Time. To receive consideration, you must submit your application electronically via Grants.gov no later than this due date and

time. If you do not submit your application by the specified deadline, we will return it to you unread. 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, HHS/Office of the Assistant Secretary for Health (OASH) Grants and Acquisitions Management (GAM) Division. To obtain an exemption, you must request one via email from the HHS/OASH/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 DUNS number; your organization's name, address and telephone number; the name and telephone number of your Authorizing Official; the Grants.gov Tracking Number (for example, 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](mailto:OASH_Grants@hhs.gov). Note: 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.

The HHS/OASH 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 F.8 (“Other Submission Requirements”) for information on application submission mechanisms.

Executive Order 12372 comment due date: 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.

To ensure adequate time to submit your application successfully, HHS/OASH recommends that you register as early as possible in Grants.gov since the registration process can take up to one

month. You must register an authorizing official for your organization. HHS/OASH does not determine your organization's authorizing official; your organization makes that designation. For information on registering for Grants.gov, refer to <http://www.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](mailto: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.

## **2. Technical Assistance**

A technical assistance webinar for potential applicants will be held May 5, 2021 at 3:00 PM Eastern. Login details will be posted at <https://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.

## **B. PROGRAM DESCRIPTION:**

The Office of the Assistant Secretary for Health (OASH) and the Office of Minority Health (OMH) announce the availability of funds for Fiscal Year (FY) 2021 under the authority of 42 U.S.C. § 300u-6 (Section 1707 of the Public Health Service Act). OMH is dedicated to improving the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities. Through its demonstration grants, OMH supports the identification of effective approaches for improving health outcomes with the ultimate goal of promoting dissemination and sustainability of these approaches. This grant is aligned with the OASH priority on health disparities and HHS Strategic Goal 4: Foster sound, sustained advances in the sciences.(1)

### **1. Background**

OMH has supported programs to address lupus disparities since 2009. Under this Lupus Program funding opportunity, OMH 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.

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.(2) 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 system lupus erythematosus (SLE), which affects different parts of the body including internal organs, joints, skin, brain, lungs, kidneys, and blood vessels.(3) 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 also differences by gender. African Americans are three to four times more likely to develop lupus than non-Hispanic whites.(4) 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.(5) Other studies show that SLE rates among American Indians and Alaska Natives (AI/ANs) are similar or higher rates than rates among African Americans.(6) The onset of lupus may occur at any age, including among young children or the elderly; however, women of childbearing age (between 15 to 44 years old) are at the highest risk of onset.(7) Women are far more likely to have lupus than men at an estimated ratio of 12 to 1.(5) Women of color—African Americans, Hispanics/Latinos, AI/ANs, and APIs—are two to three times more likely to have lupus than white women.(8) Recent studies indicate that one in 537 young African American women have lupus.(8) 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.(8)

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.(9) Though many opportunities to participate in clinical trials exist, clinical trials for lupus have had limited success in recruiting minority participants.(10,11) This challenge is in line with the underrepresentation of racial and ethnic minority populations in clinical trials in general.(12) A recent study of national and international randomized controlled trials with lupus patients calculated that only 14 percent 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.(13) 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.(14) 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.(15)

To increase participation in clinical trials, researchers have studied the barriers to participation in medical research, but there are few evidence-supported intervention 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
- Lack of participant understanding about clinical trials and the perceived direct or indirect benefits of medical research
- Perceptions and biases of health providers about minority participation in clinical trials
- Provider lack of knowledge or awareness of clinical trials
- Logistical challenges of providers referring patients to clinical trials (time with patients, connection with clinical trials, proximity of clinical trial site) (12)

- Clinical trial sites not in areas where minorities receive their healthcare (16)
- Clinical trial sponsors not utilizing trusted voices in the community to recruit participants (16)

A recent report organized lupus intervention models to address provider and patient-side barriers to participation in clinical trials into four categories: 1) Provider-focused education interventions, 2) Partnership-based interventions, 3) Patient-mediated interventions, and 4) Peer-mediated interventions.(12) OMH has supported the use of “partnership-based interventions” in other programs that include community health workers (CHWs) and promotores de salud, who provide education and connect patients to services by helping them overcome barriers in their communities and health systems. CHWs often come from the minority communities they serve and are able to provide culturally and linguistically responsive services. Clinical trials that use recruitment and retention strategies that involve CHWs have increased enrollment of racial and ethnic minority populations and decreased refusal by minority populations.(19,20) Thus, CHWs and their national, state and/or local professional associations should play an integral part in this Lupus Program.

## **2. Expectations**

The Lupus Program supports a multifaceted approach to increase minority participation in clinical trials. Effective interventions that address provider and patient-side barriers to minority participation in lupus clinical trials should be developed and implemented within minority communities. It is important that these interventions support the development of relationships with minority individuals with lupus and local health providers that work directly with minority populations. OMH expects recipients to:

- a. Develop and Implement a Disparity Impact Statement

OMH expects recipients to develop a disparity impact statement using local data, whenever possible, to identify racial and ethnic minority populations at highest risk for health disparities relevant to this initiative. The disparity impact statement will provide the contextual and measurement framework for ongoing monitoring and determining the impact of the project activities on outcomes and the overarching goal of advancing health equity. Disparity impact

statements will be required within 30 days following the issuance of any award made under this announcement.. The disparity impact statement requirement aligns with expectations related to Executive Order 13985 “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” (<https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>). See Appendix C – Disparity Impact Statement for details and resources.

b. Develop Public-Private and Community Partnerships

OMH expects the recipient to utilize standard practices necessary for establishing and sustaining effective collaborative partnerships, including public-private and community partnerships. This includes developing a structure for involvement, regularly engaging community and partnering organizations in the design and review of outreach or education interventions to be tested through this Lupus Program, and leveraging the strengths of each partner organization without duplication of effort. 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.

Applicants must demonstrate that the proposed project involves a collaborative partnership with at least two partners, one of which 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 CHWs
- Tribe or tribal organization

c. Use and Disseminate Existing Resources

Funding for the initiative is limited to supporting interventions that use and disseminate existing materials or resources and not the development of new materials or resources. OMH highly encourages the use and dissemination of resources developed as a result of previous OMH-supported lupus programs and projects to achieve expected program outcomes. Resources developed from OMH-supported programs and projects can be found through the following sites:

- 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 Medical 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-and-collaborations/increasing-minority-participation-and-awareness-in-clinical-trials>
- New Jersey Chapter, American Academy of Pediatrics, <https://njaap.org/programs/lupus/resources/>
- Lupus Research Alliance, <https://www.lupusresearch.org/>

Resources that were not developed from OMH-supported programs and projects can be used under the Lupus program. Justification for use and evidence of effectiveness should be provided for resources developed outside of OMH-supported programs and projects.

d. Tailor Existing Intervention(s)

OMH expects recipients to tailor an existing intervention to increase minority participation in clinical trials for the intended population of focus, and to implement the tailored intervention. The tailored intervention(s) should be implemented in racial and ethnic minority communities within cities and/or counties where lupus clinical trials are recruiting patients. Interventions may include:

- Provider 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 for CHWs to increase racial and ethnic minority enrollment and retention in lupus clinical trials
- Lupus clinical trial education models for minority populations

e. Implement a Process and Outcomes Evaluation

OMH expects projects to implement a rigorous evaluation to assess the impact of project activities. OMH expects recipients to 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, OMH expects recipients to 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 plan should clearly demonstrate that evaluation of the impact of the intervention will be able to detect a statistically significant difference on key project outcomes, if such impact is present. The evaluation design should control for threats to validity. OMH expects the impact analysis of the intervention to be conducted within the project period.

f. Document and Disseminate Project Findings

OMH anticipates 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. OMH expects 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.

g. Develop a Sustainability Plan

OMH expects the recipient to develop an effective plan to sustain successful interventions after the award period. Recipients should engage key stakeholders/partners in the development of the sustainability plan. Recipients should develop a sustainability plan within one year following the award. The sustainability plan should include key activities, milestones, responsible staff, and resources for implementing the project activities. OMH expects successful projects (i.e., projects demonstrating significant differences in key outcomes) to begin implementing the sustainability plan in year two.

### C. AUTHORITY

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

### D. FEDERAL AWARD INFORMATION

The Office of Minority Health intends to make funds available for competing grant awards.

We will fund awards in annual increments (budget periods) and generally for a period of performance up to two years, 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. 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:** 4-6

**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:** September 1, 2021

**Estimated Period of Performance:** Not to exceed 2 years

**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

## **E. 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/Alaska Native/Native American (AI/AN/NA) organizations are eligible to apply. Examples of eligible institutions 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 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
- Private nonprofit institutions of higher education
- U.S. territories

### **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 F.3.b.1.t. 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 F.3.b.1.s. Any change in the obligation to provide cost sharing or matching at that level will require prior approval of the grants management officer.

### **3. Application Disqualification Criteria**

If you successfully submit an application, we will screen it to ensure it meets the below requirements. 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 [www.grants.gov](http://www.grants.gov) (unless an exemption was granted 2 business days prior to the deadline) by the date and time indicated in the DATES section (A.1) 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) HHS/OASH/GAM deems your application eligible according to section E.1 Eligible Applicants.
- (d) You must complete the required forms in the application package: SF-424, SF-424A, SF-424B, SF-LLL, and Project Abstract Summary.
- (e) Your Project Narrative section of the application must be double-spaced, on the equivalent of 8 ½ ” x 11” inch page size, with 1” margins on all sides (top, bottom, left and right) and font size not less than 12 points.

- (f) Your Project Narrative must not exceed 50 pages. NOTE: The following items do not count toward the Project Narrative page limit: all required forms, including SF-424, SF-424A, SF-424B, SF-LLL, Project Abstract Summary, and Budget Narrative (including budget tables).
- (g) Your total application, including the Project Narrative plus Appendices, must not exceed 75 pages. NOTE: items listed in “(f)” immediately above do not count toward total page limit.
- (h) Your Federal funds request including indirect costs must not exceed the maximum indicated in Award Ceiling.
- (i) Your Federal funds request including indirect costs must not be below the minimum indicated in Award Floor.

## **F. APPLICATION AND SUBMISSION INFORMATION**

### **1. Address to Request Application Package**

You may obtain an application package electronically by accessing Grants.gov at <http://www.grants.gov/>. You can find it by searching on the CFDA number shown on page 2 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](mailto: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.

The Project Narrative, and total application including appendices, must adhere to the page limit indicated in Application Disqualification Criteria listed in Section C. The page limit does not include the Budget Narrative (including budget tables), required forms, assurances, and certifications as described in the Application Disqualification Criteria. 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 when printed on 8.5” X 11” paper by HHS/OASH/GAM, we will not review it. We recommend you print out your application before submitting electronically to ensure that it is within the page limits and is easy to read.

You must double-space the Project Narrative pages.

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.

b. Appendices Format

Your Appendices should include any specific documents outlined in Section D.2.iii., under the heading “Appendices” in the Application Content section of this funding opportunity announcement. Your documents should be easy to read. You should use the same formatting specified for the Project Narrative. However, documents such as résumés/CVs, 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. If your project is funded, HHS may publish information from your form; therefore, do not include sensitive or proprietary information.

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. HHS/OASH recommends that your project narrative include the following components: 1) Problem Statement; 2) Organizational Capacity; 3) Project Plan; 4) Evaluation Plan; 5) Dissemination Plan; 6) Sustainability Plan

1) Problem Statement

Describe the scope of the problem that will be addressed by the proposed project, including the population(s) and geographic area of focus and the disproportionate impact on racial and ethnic minority populations in the geographic area of focus. Provide a table, as an appendix, using quantitative data to describe the population(s) of focus at highest risk for experiencing disparities, by race and ethnicity. Identify and define the problem, and contributing factors to the problem, that will be addressed by the proposed project activities. Describe the need for the proposed intervention for increasing minority participation in lupus clinical trials. Detail how the project will potentially affect the populations served, specific subgroups within those populations, and other interested stakeholders as identified. You should detail how the project will affect racial and ethnic minority groups. In addition, the problem statement should:

- For the population(s) of focus:

- Provide lupus-specific epidemiology data that describes the need
- Provide clinical trial data that describes the need
- Describe the barriers to clinical trial participation for the population(s) of focus
- Provide data that describes the need for providers to have increased access to and increased participation in lupus clinical trial education/training
- Provide data that describes the need for public-private partnerships and community partnerships to support and/or sustain project activities
- Describe the problem concerning lupus in each selected geographic area.

## 2) Organizational Capacity

The organizational capacity statement should describe how the applicant (or the particular division of a larger agency which will have responsibility for this project) is organized, the nature and scope of its work, and the capabilities it possesses. Describe current or previous relevant experience, including significant experience working on lupus and with minority populations. Documentation of experiences should include a brief synopsis regarding any lupus project funding currently received or received within the past five years, a brief description of the intervention supported through the project(s), and project outcomes. Describe the organization's readiness for implementing the project and achieving measurable outcomes in the period of performance.

Describe areas of expertise for key personnel. Provide vitae or biographical sketches for key project personnel in the Appendices, as described in Section F.3.c. Key personnel include the Principal Investigator/Project Director and Evaluator for the project. The organizational capacity section should also document significant knowledge and expertise in issues related to clinical trials to support developing and implementing effective outreach or education interventions regarding lupus clinical trials. This section should also document significant knowledge and expertise in lupus epidemiology, diagnosis, treatment, and disparity-related issues. This section should unambiguously identify the individuals/organizations responsible for evaluation activities and that

individual/organization's qualifications. Describe the relationship between the evaluator and the organization and the degree of independence the evaluator will have.

This section should include an organizational chart showing the relationship of the project to the current organization and include the organizational chart in the Appendices. This chart may also include the contractual and/or supportive organizations that will become part of the network. Also, information about 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.

The organizational capacity section should describe experience and expertise in:

- Providing outreach to and education of minority populations with lupus
- Providing lupus clinical trial outreach, education and training to health care providers and/or paraprofessionals, such as CHWs
- Evaluation of outreach, education and training programs related to recruitment and participation in clinical trials
- Working with individuals and families affected by lupus
- 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 existing public-private and community partnerships relevant for the proposed project, and partner roles and responsibilities. Describe the existing or proposed partnership(s) with:

- 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, or CHWs; or
- Tribe or tribal organization.

To the extent possible, the applicant should provide documentation of the level of commitment of any partners in the Appendices, as described in Section F.3.c.

### 3) Project Plan

#### (a) Goals, Objectives and Outcomes

The project plan should describe the overall project goals, annual short-term and long-term objectives. It must also provide sufficient description of the magnitude of impact on intervention outcomes and performance measure objectives for the proposed activities. SMART (specific, measurable, accurate, realistic and timely) objectives should include baseline data and quantifiable timeframes for achievement. Intervention objectives must describe the overall goals of the project rather than project activities. Goals must be ambitious and achievable in the project's timeframe/project period. This section should clearly identify the measurable outcome(s) that will result from the project, and provide specific, quantified estimate of expected outcome(s). HHS/OASH will not fund any project that does not include measurable outcomes. In addition to discussion in the narrative, the proposal should describe how the applicant envisions the project will benefit the field, targeted population and society (i.e., significance of the project).

This section of the project narrative must clearly identify the measurable outcome(s) that will result from the project. HHS/OASH 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. In addition to discussion in the narrative, the project must describe how it envisions the project will benefit the field at large.

#### (b) Intervention

Describe how the project will address health disparities among racial and ethnic minority populations to promote health equity, including the projected impact of project activities on these populations. Describe your approach for developing the disparity impact statement, including the identification of the disparate population(s). The approach for disparity impact statement development should include a description of how you will use program implementation data and apply the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (National CLAS Standards) to support quality improvement and ensure the project is implemented in a culturally appropriate manner (<https://thinkculturalhealth.hhs.gov/clas/standards>).

Provide a clear description of the proposed existing outreach or education intervention for increasing minority participation in lupus-related clinical trials. The description must clearly explain the rationale for using a particular intervention, and present a clear connection between identified evidence gaps and needs and proposed project activities. Provide the reasoning for selecting the intervention. Describe how the intervention will be tailored for the population(s) of focus. This section should also describe specific practices to be used in the proposed intervention in relation to the problem and factor(s) to be addressed. Describe the expected intervention participants and provide rationale for the focus on these participants. The project plan should describe the approach for recruiting, enrolling and retaining intervention participants. This section should describe how the proposed intervention is culturally and linguistically appropriate for the population of focus.

The project plan should describe readiness to implement the intervention(s) or practice(s). This section should describe how the intervention will be carried out and the role(s) of any collaborating organizations or subrecipients. This section should also describe how the project will increase provider and/or minority participation and address barriers to minority participation in lupus clinical trials. In addition, the description should identify any major barriers anticipated and how the project will be able to overcome those barriers.

(c) Work Plan

You must provide a detailed summary of activities to be undertaken and how they will assist in achieving the project goals and objectives. The plan should describe the approach that will be used to monitor and track progress on the project's tasks and objectives. It should also include a work plan describing how the project will be accomplished. The work plan should reflect, and be consistent with, the Project Narrative and Budget Narrative, and must cover all years of the project period. 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, the work plan should identify the timeframes involved (including start- and end-dates), and the lead person responsible for completing the task. In addition:

- Describe the proposed approach for development of public-private and community partnerships and related activities.
- Describe the strategies that will be used to working with partners to achieve Lupus Program goals.
- Describe the proposed approach for disseminating and using resources developed in previous OMH-funded lupus programs and related activities.

#### 4) Evaluation Plan

Provide a process and outcomes evaluation plan for the project. The evaluation plan should describe:

- The evaluation approach that will be used to determine whether the project reached its population(s) of focus described in the Disparity Impact Statement.
- How your evaluation will demonstrate the equity impact of the project on the disparate racial and ethnic minority populations and the identified health disparities.
- Your evaluation design in detail, and how your evaluation design will clearly establish whether project activities result in the intended outcome.
- How your evaluation design controls for threats to validity.
- How your evaluation design a) will be able to show a statistically significant impact of your intervention on the key outcomes, or b) employs Bayesian analysis and estimation to assess the impact of your intervention on outcomes, including all relevant calculations.
- The data you will collect and use to ensure the project activities are achieving their intended objectives and outcomes.
- Your proposed measures/indicators to monitor and document key project outcome(s), detailing the validity and reliability of proposed measures/indicators.

- The methods you will use to collect your data, including performance measurement data, and how you will overcome any potential obstacles to data collection.
- Your approach for collecting, at minimum, baseline, interim, and post-intervention process and outcome measures.
- How you will evaluate all project components of the project's logic model, including how the inputs, processes, outputs and outcomes will be measured.
- How your evaluation will assess the extent to which the intervention(s) increased racial and ethnic minority enrollment and retention in lupus clinical trials.
- How the project will involve partners in evaluation activities.

Submit a detailed logic model that demonstrates linkages between the disparity impact statement, objectives, activities, outputs, and outcomes, as an Appendix as described below (Section F.3.c).

#### 5) Dissemination Plan

This section should describe the method that will be used to document and disseminate the project's results and findings in a timely manner and in easily understandable formats to the target audience, the general public, and other parties who might be interested in using the results of the project. All appropriate findings and products may be posted on a HHS/OMH sponsored website as determined by HHS/OMH. Therefore, the project should propose other innovative approaches to informing parties who might be interested in using the results of the project to inform practice, service delivery, program development, and/or policy-making, especially to those parties who would be interested in replicating the project. HHS/OMH expects that nationwide dissemination of products and knowledge will occur.

#### 6) Sustainability Plan

Describe your approach for developing a sustainability plan that provides a concrete set of action steps necessary for beginning and maintaining elements of collaboration that contributed to

successful outcomes after the award. Describe how you will identify key individuals and/or organization(s) whose support will be required in order to sustain activities. Describe your strategies for identifying and securing financial, staff and supervisory, and material resources that will sustain and support continued implementation of efforts beyond the end of the project. Describe existing collaborative partnership with organizations that might embed the effort within their routine operations or provide other support for sustaining successful activities.

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. You must indicate the method you are selecting for your indirect cost rate. See Indirect Costs below for further information.

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).

Please be sure to carefully review section F.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. Provide a budget justification, which includes explanatory text and line-item detail, for the 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, provide a summary narrative and line item budget. For categories or items that differ significantly from the first budget year, provide a detailed justification explaining these changes. Note, **do not** include costs beyond the first budget year 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 year.

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. For example, if you are proposing to provide services to clients, you should describe how many clients are you expecting 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 (when required) must be detailed and justified in the budget narrative. "Federal resources" refers only to the HHS/OASH funds for which you are applying. "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.

Sample Budget Table

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

Note, subrecipient/contract and consultant detailed costs should all be included in those specific line items, not in the overall project object class line items, i.e., subrecipient travel should be included in the Contractual line item not in Travel.

1) Object Class Descriptions and Required Justifications

(a) Personnel Description

Costs of staff salaries and wages, excluding benefits.

(b) Personnel Justification

Clearly identify the project director or principal investigator, 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 F.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.

Sample Personnel Table

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, Susan R. Smith	10%	\$30,000		\$3,000	\$3,000

(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.

(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.

(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. (Note: 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 2 C.F.R. § 200.1 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 2 C.F.R. § 200.320 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.

Note: Whenever you intend to delegate part of the project to another agency, you must provide a detailed budget and budget narrative for each subrecipient/contractor, by agency title, 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 delegated, the estimated costs, and the process for selecting the delegate agency.

(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.

- i. 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.
- ii. 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 § 200.403, 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.”  
This 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.

(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, 2 C.F.R. §200.407 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. Unless being used for cost sharing, if applicable, these funds should not be added to your budget. 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 2 C.F.R. § 200.306.

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). Your failure to provide voluntary cost sharing of non-federal resources that have been accepted by HHS/OASH as part of the approved project costs and that are shown as part of the approved project budget in the NOA 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. Note, 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). **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.**

2) Plan for 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, you may provide the link as part of your plan in the budget narrative. We have also included, in Appendix A, questions applicants may find useful to consider when developing their Plan 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) Supplemental Information/Supporting Documentation for Work Plan

Include any supplemental information or supporting documentation for your work plan.

2) Project Population(s) of Focus

Submit a table outlining the population(s) of focus within the identified geographic area of focus using quantitative data. The data should include racial/ethnic minority populations.

3) Organizational Chart

The applicant must submit with its application an organizational chart that shows the relationship of the project to the current organization. All personnel involved in the program (paid and/or volunteer) should be included in the organizational chart. The organizational chart should

clearly delineate the implementation roles and responsibilities of both the applicant organization and each partner organization. The organizational chart should make clear the unique contributions of each organization to the intervention and/or evaluation.

4) Memorandums of Agreement and/or Letters of Commitment from Partners, Subrecipient Organizations, and Agencies.

If available at the time of submission, signed MOAs or signed Letters of Commitment (LOCs) may be submitted for each partner (or one signed MOA with all partners) and include specific roles, responsibilities, resources, and contributions of partner(s) to the project. If the applicant is unable to submit signed MOAs, the applicant should submit an unsigned MOA(s). The 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 will be required within 30 days following the issuance of any award made under this announcement.

Letters of commitment 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, and letters of support such as this will not be considered during the review.

5) Curriculum Vitae/Résumé for Key Project Personnel

You must submit with your application curriculum vitae and/or résumés of the Project Director/Principal Investigator, Evaluator and all other Key Personnel. Key Personnel includes those individuals who will oversee the technical, professional, managerial, and support functions and/or assume responsibility for assuring the validity and quality of your organization's program. This includes at a minimum Program Manager/Program Coordinator. We encourage individuals to use their full name (first, middle, last) on these documents to distinguish them for verification in the System for Award Management exclusion records.

6) Logic Model

The applicant must submit with its application a Logic Model that specifies and describes the program theory to be employed in the intervention. All program objectives, activities and outcomes must be reflected in the logic model and demonstrate that the proposed project reflects

a coherent approach. The logic model should clearly describe how the project will evaluate all project components, including how the inputs, processes and outcomes will be measured and how the knowledge gained will increase minority participation in lupus clinical trials. The logic model should describe the systems and processes that will support the organization's performance management through effective tracking of performance outcomes.

#### 7) Just in Time Institutional Review Board Agreement

The applicant must submit with the application a signed letter by the authorized official assuring that, if funded, the applicant will submit an application to an Institutional Review Board for approval.

Recipients must comply with all HHS regulations, including those governing protection of human subjects (See Section H.14). You may find more information online at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

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

You are required to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for Federal awards through Grants.gov. It is a unique, nine-digit identification number, which provides unique identifiers of single business entities. The DUNS number is free and easy to obtain.

You will find instructions on the Grants.Gov web site as part of the organization registration process at <http://www.grants.gov/web/grants/applicants/organization-registration.html>.

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.

If 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=KB0020386&sys\\_kb\\_id=44b59da51b9ea01005f9a93ce54bcbe2&spa=1](https://www.fsd.gov/gsafsd_sp?id=kb_article_view&sysparm_article=KB0020386&sys_kb_id=44b59da51b9ea01005f9a93ce54bcbe2&spa=1).

A quick start guide for registrants is available at [https://www.sam.gov/SAM/transcript/Quick\\_Guide\\_for\\_Grants\\_Registrations.pdf](https://www.sam.gov/SAM/transcript/Quick_Guide_for_Grants_Registrations.pdf). 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.

If your organization is already registered in SAM, 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.

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, this information must be included on a Notice of Award. For instructions on updating this information see [https://www.sam.gov/SAM/transcript/Quick\\_Guide\\_for\\_Updating\\_or\\_Renewing\\_SAM\\_Registrations.pdf](https://www.sam.gov/SAM/transcript/Quick_Guide_for_Updating_or_Renewing_SAM_Registrations.pdf).

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.

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.

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 DUNS number at the time you, the recipient, make a sub-award.

## **5. Submission Dates and Times**

You must submit your application for this funding opportunity by **the date and time indicated in Section A.1 of this announcement**. 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 <http://www.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.**

## **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 2 C.F.R. part 200 “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal 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 the Budget Narrative section of this announcement 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>.

### **1) Pre-Award Costs**

Pre-award costs (per 2 C.F.R. § 200.458) 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. Such costs are allowable only to the extent that they would have been allowable if incurred after the date of the Federal award and only with the written approval of the HHS awarding agency.

**Pre-award costs are NOT allowed.**

### **2) 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 2021, the Executive Level II salary is \$199,300. 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 <i>actual</i> 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 <i>adjusted</i> to Executive Level II: \$199,300 with 50% of time devoted to the project	
Direct salary (\$199,300 x 0.5)	\$99,650
Fringe (25% of salary)	\$24,913
Total amount allowed	\$124,563

Appropriate salary rate limits will apply as required by law.

## 8. Other Submission Requirements

### a. Electronic Submission

HHS/OASH requires 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 <http://www.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. HHS/OASH strongly recommends 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. Please note, even though Grants.gov allows you to attach any file format as part of your application, HHS/OASH restricts this practice and only accepts the file formats identified above. 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.

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 information in the application will not be forwarded for consideration.

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 <http://www.grants.gov>. You must search the downloadable application page by the Funding Opportunity Number or 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 Contacts below. See Section F.4 for requirements related to DUNS numbers and SAM registration.

## G. 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. Problem Statement (10 Points)

- How well did the applicant describe the scope of the problem that will be addressed by the proposed project, including the population(s) and

geographic area of focus and the disproportionate impact on racial and ethnic minority populations and proposed reach of project activities?

- How well did the applicant demonstrate strong need for the proposed intervention for increasing minority participation in lupus clinical trials?
- How well did the applicant describe the barriers to clinical trial participation for the population(s) of focus?
- How well did the applicant provide data that describes the need for providers to have increased access to and increased participation in lupus clinical trial education/training?
- How well did the applicant provide data that describes the need for public-private partnerships and community partnerships to support and/or sustain project activities?
- How well are the geographic area(s) of focus aligned with the population(s) of focus?

b. Organizational Capacity (20 Points)

- To what extent did the applicant clearly identify the individual/organization responsible for evaluation activities? To what extent are the individual's/organization's qualifications adequate for conducting the evaluation successfully?
- To what extent did the applicant describe an adequate degree of independence of the evaluator from the applicant organization?
- To what extent did the applicant clearly describe current or previous relevant experience, including significant experience working on lupus and with minority populations?
- To what extent did the applicant document experience that includes a brief synopsis regarding any lupus project funding currently received or received within the past five years, a brief description of the intervention supported through the project(s), and project outcomes?

- To what extent did the applicant describe significant experience working on lupus and with minority populations?
- To what extent did the applicant describe the organization's readiness for implementing the project and achieving measurable outcomes in the period of performance?
- To what extent did the applicant demonstrate significant knowledge and expertise in issues related to clinical trials to support developing and implementing effective intervention and education models regarding lupus clinical trials?
- To what extent did the applicant demonstrate significant knowledge and expertise in lupus epidemiology, diagnosis, treatment, disparity-related issues, outreach, education, working with families, working with patient advocates, and evaluation of education/training?
- To what extent did the applicant demonstrate adequate existing and proposed partnerships to support the goals and objectives? To what extent did the applicant demonstrate it possesses the necessary public-private and community partnerships in place to conduct the intervention? To what extent did the applicant demonstrate a partnership(s) with:
  - 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, or CHWs; or
  - Tribe or tribal organization?

c. Project Plan (30 Points)

- To what extent did the applicant describe of the magnitude of impact on intervention outcomes and performance measure objectives for the proposed activities?

- To what extent did the applicant provide SMART objectives that describe the overall goals of the project rather than project activities?
- How well does the applicant’s approach for developing a disparity impact statement address:
  - Use of appropriate datasets to provide baseline, disaggregated data supporting the identification of population(s) of focus and related health disparities?
  - Strategies to address the identified health disparities?
  - Application of the National CLAS Standards?
  - An ongoing quality improvement process to address the identified disparities?
- How adequately does the applicant describe the projected impact of the project on racial and ethnic minority populations and on the identified health disparities, and level of impact expected?
- How well did the applicant describe the proposed outreach or education intervention for increasing minority participation in lupus-related clinical trials? Is it an existing intervention? How well does the proposed intervention align with the project goals and objectives?
- To what extent did the applicant clearly explain the rationale for using a particular intervention, and present a clear connection between identified evidence gaps and needs and proposed project activities?
- How well did the applicant describe how the intervention will be tailored for the population(s) of focus, and to what extent are the proposed changes appropriate for the population(s) of focus?
- How well did the applicant describe the expected intervention participants and demonstrate the need for the expected participants to receive education, outreach and/or training?
- To what extent did the applicant describe how the proposed intervention is culturally and linguistically appropriate for the population of focus?
- To what extent did the applicant demonstrate readiness to implement the intervention?

- To what extent did the applicant describe how the project will increase provider and/or minority participation and address barriers to minority participation in lupus clinical trials?
- To what extent did the applicant provide a comprehensive detailed project plan that describes proposed implementation and approaches including activities?
- How feasible and adequate is the applicant's proposed approach for development of public-private and community partnerships?
- To what extent did the applicant include effective strategies for working with partners to achieve Lupus Program programmatic goals?
- How feasible and comprehensive is the applicant's proposed approach for the use and dissemination resources developed in previous OMH-funded lupus programs and related activities?
- How well does the project plan reflect the Project Narrative and Budget? How consistent is the project plan with the Project Narrative and Budget?
- How clearly and logically does the work plan state the project's overall result-based goals, anticipated outcomes, key objectives, and the major tasks/action steps that will be pursued to achieve the goal and outcome(s)?
- How thoroughly does the work plan include components to evaluate progress toward achieving the applicant's stated goals and outcomes?
- How feasible and specific are the work plan's specified timeframes (including start- and end-dates) to meet project goals and objectives? How clearly does the work plan identify the lead person (including partners/consultants) responsible for completing each task?
- Does the evaluation section of the Work Plan establish clear, achievable data collection milestones?

d. Evaluation Plan (25 Points)

The application will be assessed based on the degree to which the evaluation plan:

- Describes a feasible evaluation approach for determining whether the project reached its population(s) of focus described in the Disparity Impact Statement
- Describes a feasible and rigorous evaluation approach for effectively demonstrating any impact of the project on racial and ethnic minority populations and on health disparities
- Describes a rigorous evaluation design that will clearly establish whether project activities result in the intended outcomes
- Adequately controls for threats to validity
- Is designed to show a statistically significant impact of your intervention on the key outcomes, or employs Bayesian analysis and estimation to assess the impact of your intervention on outcomes
- Demonstrates how the data collected will be used to clearly assess how project activities are achieving their intended objectives and outcomes
- Describes a feasible approach for collecting baseline, interim, and post-intervention process and outcome measures
- Specifies widely accepted public health/social science methods for data collection, including performance measurement data, and describes a feasible plan for overcoming any potential obstacles to data collection
- Employs proposed measures/indicators with established validity and reliability assessments to monitor and document key project outcome(s)
- Adequately evaluates all project components of the project's logic model, including how the inputs, processes, outputs and outcomes will be measured
- Specifies a rigorous and appropriate methods for assessing the extent to which the intervention increased racial and ethnic minority enrollment and retention in lupus clinical trials

e. Dissemination Plan (5 Points)

- To what extent did the applicant describe an approach which will lead to the documentation and dissemination of the project's results and findings in a timely manner and in easily understandable formats to the target audience, the general public, and other parties who might be interested in using the results of the project?

f. Sustainability Plan (10 Points)

- To what extent did the applicant describe a work plan and/or capacity to develop an effective plan to sustain successful interventions after the award period?
- To what extent does the applicant describe a feasible approach for developing a sustainability plan to support continued implementation of successful interventions beyond the grant period?
- How feasible are the applicant's strategies for securing policy, financial, staff and supervisory and/or material resources needed for continued implementation of successful interventions?
- To what extent does the applicant document existing collaborative partnership with organizations that might embed the interventions(s) within their operations or provide other support for sustaining successful interventions?

## **2. Review and Selection Process**

Each HHS/OASH Program's office is responsible for facilitating the process of evaluating applications and setting funding levels according to the criteria set forth above.

An independent review panel will evaluate applications that meet the responsiveness criteria, if applicable, and are not disqualified. 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 score the applications, focusing their comments and scoring decisions 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.

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

- Equitable geographic distribution of projects

### **3. Review of Risk Posed by Applicant**

The HHS/OASH will evaluate, in accordance with 2 C.F.R. § 200.206, 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. OASH 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 2 C.F.R. part 200;
- 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 2 C.F.R. § 200.206(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.” 2 C.F.R. § 200.206(a)(2); see also 2 C.F.R. §200.213 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, HHS/OASH will issue Notices of Award. No award decision is final until a Notice of Award is issued. All award decisions, including level of funding if an award is made, are final and you may not appeal.

HHS/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.

## **H. FEDERAL AWARD ADMINISTRATION INFORMATION**

### **1. Federal Award Notices**

HHS/ OASH does not release information about individual applications during the review process. If you would like to track your application, please see instructions at <http://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 of the HHS/OASH GAM. If you are successful, you will receive this document via 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 HHS/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. On occasion, you may receive a letter indicating that an application was approved but unfunded. These applications may be kept active for one year and may be considered for award without re-competing should funds become available during the hold period.

### **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 2 C.F.R. part 200, 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 <http://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 have been superseded by 45 C.F.R. part 75 and 2 C.F.R. part 200.

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 2 C.F.R. § 200.308 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.

### **3. Closeout of Award**

Upon expiration of your period of performance, if we do not receive acceptable final performance, financial, and/or cash reports in a timely fashion within the closeout period, and we determine that closeout cannot be completed with your cooperation or that of the Principal Investigator/ Project Director, we must complete a unilateral closeout with the information available to us. (See H.14 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.

#### **4. 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.

## **5. Non-Discrimination Requirements**

Pursuant to Federal civil rights laws, if you receive an award under this announcement you must not discriminate on the basis of race, color, national origin, disability, age, and in some cases sex and religion. The HHS Office for Civil Rights provides guidance for complying with civil rights laws that prohibit discrimination. <https://www.hhs.gov/civil-rights/index.html>.

HHS provides guidance to recipients of federal financial assistance on meeting the legal obligation to take reasonable steps to provide meaningful access to persons with limited English proficiency. See *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, 68 Fed. Reg. 47311, 47313 (HHS Office for Civil Rights, 2003, [www.gpo.gov/fdsys/pkg/FR-2003-08-08/pdf/03-20179.pdf](http://www.gpo.gov/fdsys/pkg/FR-2003-08-08/pdf/03-20179.pdf)) You must ensure your contractors and subrecipients also comply with federal civil rights laws.

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, <http://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. Compliance with the National CLAS Standards meets the legal obligation to take reasonable steps to provide meaningful access to persons with limited English proficiency.

## **6. 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.

## **7. 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 Office of Minority Health/OASH/HHS.

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, Office of Minority Health/OASH/HHS, or the U.S. Government. For more information, please visit <https://minorityhealth.hhs.gov>.

## **8. 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.

## **9. Trafficking in Persons**

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

## **10. 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 <http://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/>.

## **11. 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.

## **12. 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).

- 1) 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).
- 2) Telecommunications or video surveillance services provided by such entities or using such equipment.
- 3) 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.

### **13. 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. You may find it online at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

Applicants 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 [www.hhs.gov/about-research-participation](http://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.

#### **14. 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 <http://ori.hhs.gov/assurance-program>.

#### **15. Reporting**

##### **a. Performance Reports**

You must submit performance reports on a quarterly basis. Your performance reports must address content required by 2 C.F.R. § 200.329(c)(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), in the Grant Notes module.

You will also be required to submit a final performance report covering the entire period of performance 90 days after the end of the period of performance. You must submit the final report by upload to our grants management system (GrantSolutions.gov), in the Grant Notes module.

b. Performance Measures

In addition to the submission of quarterly reports in our grants management system, OMH expects awardees to report program process and outcome data electronically to OMH on a quarterly basis. Performance process and outcome data allow OMH to evaluate the performance of its initiatives across awardees. All OMH awardees under this initiative are required to report project performance process and outcome data on a quarterly basis through Grant Solutions. No performance measure reporting will be required without OMB approval. Training will be provided to all new grantees on the collection and reporting of performance data during the Technical Assistance and Training grantee meeting.

Note: Recipients may be required to report project-related data in the Office of Minority Health's Performance Data System (PDS) (OMB No. 0990-0275, Expiration date 8/31/2022).

At the end of each quarter of this initiative, you should be able to:

- 1) Describe accomplishments and progress toward program purpose/strategies/interventions and disparity impact statement.
- 2) Summarize the status of the project's staffing situation.
- 3) Describe the role and activities of each partnering organization.
- 4) Describe 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 90 days after the end of the period of performance. You must submit FFRs via our grants management system (GrantSolutions.gov) FFR module.

Quarterly cash reporting to the HHS Payment Management System on the FFR is also required. Please note, at this time, these FFR reports are separate submissions via the Payment Management System. At this time, data is not transferable between the two systems and you will report twice on certain data elements.

d. Audits

If your organization receives \$750,000 or greater in Federal funds, it must undergo an independent audit in accordance with 2 C.F.R. part 200, 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. HHS/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. Additionally, 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 (<http://www.FSRS.gov>) for all sub-awards and sub-contracts issued for \$25,000 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 2 C.F.R. part 200—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 2 C.F.R. part 200.

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 HHS/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 HHS/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.

## I. 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

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.

Ramon Bonzon

1101 Wootton Parkway, Plaza Level

Rockville, MD 20852

Phone: (240) 453-2824

Email: Ramon.Bonzon@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: [www.grants.gov](http://www.grants.gov)

Phone: 1-800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov)

## J. 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)
- Assurances for Non-construction Programs (SF-424B)
- 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.**
  - Supplemental Information/Supporting Documentation for Work Plan
  - Project Population(s) of Focus
  - Organizational Chart
  - Memorandums of Agreement and/or Letters of Commitment from Partners, Subrecipient Organizations and Agencies

- Curriculum Vitae/Résumé for Key Project Personnel and Position Descriptions
- Logic Model
- Just in Time Institutional Review Board Agreement



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RADM Felicia Collins

Director, Office of Minority Health

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Date

## APPENDICES

### A. References

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## **B. Glossary**

***Disparity impact statement*** 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.

***Health disparity*** refers to a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion.(19)

***Health equity*** refers to the “attainment of the highest level of health for all people. Achieving health equity requires valuing everyone equally with focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health and health care disparities.”(19)

***National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care*** are a set of 15 action steps that provide guidance for providing health care and services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy and other communication needs. Additional information can be found here: <https://thinkculturalhealth.hhs.gov/clas>.

### C. Disparity Impact Statement

OMH's disparity impact strategy is a comprehensive data-driven approach for identifying and addressing health disparities to promote health equity for racial and ethnic minority populations. The disparity impact strategy aligns with expectations related to Executive Order 13985 "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government" (<https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>). A ***Disparity Impact Statement*** 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.

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>)
- Examples of Disparities Impact Statements (<https://www.samhsa.gov/grants/grants-management/disparity-impact-statement>)
- HDPulse — An Ecosystem of Minority Health and Health Disparities Resources (<https://www.nimhd.nih.gov/resources/hd-pulse.html>)

## **D. Considerations in Plans for Oversight of Federal Funds**

To the maximum extent possible, the 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 a 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?
  - Are bank statements promptly reconciled to the accounting records, and are they reconciled by someone other than the individuals handling cash, disbursements and maintaining accounting records?
  - Are all disbursements (except petty cash or EFT disbursements) made by pre-numbered checks?
  - Do supporting documents (e.g., purchase orders, Invoices, etc.) accompany checks submitted for signature and are they marked "paid" or otherwise prominently noted after payments are made?