U.S. Department of Health and Human Services

Office of Minority Health

Notice of Funding Opportunity

National Lupus Outreach and Clinical Trial Education Program

Opportunity Number
MP-CPI-26-001

Application Due Date
07/10/2026

Technical Assistance Webinar Date
06/24/2026

Table of Contents

BASIC INFORMATION	
Opportunity Title National Lupus Outreach and Clinical Trial Education Program	
Program Office The Office of the Assistant Secretary for Health, Office of Minority Health	**Application Submission and Format** Electronic application submitted via Grants.gov ONLY.
Opportunity Number MP-CPI-26-001	
Award Type Grant	**Application Deadline** 07/10/2026
Announcement Type Initial	**Technical Assistance Webinar Date** 06/24/2026
Assistance Listing 93.137, Community Programs to Improve Minority Health	**Technical Assistance Webinar Details** See Section F.3.C for more details
Eligible Applicants (see Section A.1 for full details)	
Executive Order 12372 does apply to this NOFO (see section E.3.D)	
Estimated Total Funding Available $3,000,000	**Estimated Period of Performance (months)** 36
Estimated Number of Awards 6	**Anticipated Award Date** 09/30/2026
Anticipated Award Funding Range $500,000	**Anticipated Project Start Date** 09/30/2026
QUESTIONS? **Additional contact information in Section G**	

SUMMARY

The Office of Minority Health (OMH) announces the anticipated availability of funds for Fiscal Year (FY) 2026 grants under the authority of Section 1707 of the Public Health Service Act (42 U.S.C. § 300u-6).

This notice solicits applications for projects to implement integrated, community-based models that increase participation of underrepresented populations in lupus clinical trials across the full participation pathway, including awareness, referral, screening, enrollment and retention.

OMH 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 their application complies with all requirements and instructions.

The Office of the Assistant Secretary for Health (OASH) Grants and Acquisitions Management Division (GAM) will administer this award.

A. ELIGIBILITY INFORMATION

□. □ligible Applicants

You must meet all the eligibility requirements for us to review your application.

a. Eligible Entities

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

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

Public or non-profit community-based organizations (CBOs) are eligible to apply. Non-profit private institutions of higher education are eligible to apply.

Other examples of eligible Organizations include:

- State governments
- County governments
- City or township governments
- Special district governments
- Independent school districts

- Public and State controlled institutions of higher education
- Native American tribal governments (Federally recognized)
- Public housing authorities/Indian housing authorities
- Native American tribal organizations (other than Federally recognized tribal governments)
- Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
- Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education

b. PD/PI Eligibility

There is no restriction on an individual's eligibility to be Project Director (PD)/Principal Investigator (PI). However, we will not make an award with a PD/PI who has an active government-wide exclusion, suspension, or debarment recorded in SAM.gov.

We expect that throughout the period of performance the PD/PI will be involved in, and have substantial knowledge about, all aspects of the project. Although your organization may recognize co-PD/PIs on team-managed projects, we recognize only a single PD/PI who will be responsible for the programmatic aspects of the project.

c. Other Considerations

Submitting Multiple Applications

You may submit more than one application, but each application must be for a distinctly different project.

If you submit multiple applications for the same project, we will accept only the last application submitted with a Grants.gov timestamp that is before the due date and time. We will disqualify all other versions of the application. See Section F.1.b for all disqualification factors.

Submitting an Application as a Group or Consortium

For any given project, we will only make an award to a single eligible entity. More than one entity may choose to work together on a project under this opportunity, but only one entity may submit the application. If awarded, that entity will be the award recipient and will be responsible for conducting the project.

The other entities may participate in the project, if awarded, and would be responsible to the recipient for their respective roles, typically as subrecipients.

Groups may form a consortium, partnership, or other legally recognized entity for the purpose of applying for this opportunity and carrying out any awarded project. The resulting entity must exist and be legally recognized when it applies and must have an active registration in SAM.gov. We will conduct a risk assessment on the applying entity (Section F.4) prior to making any award.

Eligibility Documentation

We do not require you to submit documentation of your eligibility (e.g., proof of 501(c)(3) status as determined by the Internal Revenue Service or an authorizing tribal resolution) when you submit your application. It is important that your organization is correctly classified in your SAM registration (Section E.2.a).

During our review of your application, we might request additional documentation to support your eligibility. This request means only that your application is under review and not that you will receive an award.

More specific information on the type of documentation that we might request specific to this opportunity appears in Section E.4.b.

Application Disqualification

We will disqualify applications that fail to meet the eligibility, responsiveness, formatting, and submission requirements (Sections F.1.b) prior to conducting merit review. Disqualified applications will not undergo further review.

We will notify disqualified applicants at the end of the competition when we announce the award recipients.

□. Application Responsiveness Criteria

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

The responsiveness criteria are as follows:

There are no Other - Application Responsiveness Criteria.

□. Cost Sharing or Matching

You are not required to provide cost sharing or matching in your proposed budget.

B. Agency Priorities

The recipients of this award must implement any funds awarded under this NOFO to effectuate program goals and agency priorities in accordance with the Priorities of the Office of the Assistant Secretary for Health (available online at: https://health.gov/priorities), and when authorized by law according to the OMH statute, regulations, legislative mandates, and additional program guidance. Funded activities must advance and support OASH's mission to improve the health and well-being of Americans.

In addition, the recipient is required to administer any project that is awarded under this NOFO in accordance with the following objectives in the OMH statute that are authorized to advance them:

1. Implement a Quality Improvement and Quality Assurance (QI/QA) Plan with the goal to achieve optimal health outcomes

The recipients must demonstrate ongoing compliance with these priorities, in all programs that are authorized to advance them, through program design, implementation, reporting, and evaluation. Failure to meaningfully align funded activities with the applicable requirements may result in corrective action, additional reporting requirements, or other actions consistent with federal grant regulations found at 2 C.F.R. Part 200 and the terms and conditions of this award (including termination pursuant to 2 C.F.R. 200.340(a)(4) for no longer effectuating program goals or agency priorities).

C. PROGRAM DESCRIPTION

The Office of the Assistant Secretary for Health (OASH), Office of Minority Health (OMH) announces the anticipated availability of funds for Fiscal Year (FY) 2026 grants under the authority of Section 1707 of the PHS Act (42 U.S.C. § 300u-6).

The primary focus of OASH is to lead Americans toward healthier lives by promoting health and well-being across the lifespan. Grants funded through this NOFO will:

- Reduce lupus-related adverse health outcomes by increasing participation of underrepresented populations in lupus clinical trials.
- Support outreach, education, and partnerships that move beyond awareness building to measurable participation outcomes, including screening, enrollment, and retention in lupus clinical trials.

Background

Systemic lupus erythematosus (lupus) is a chronic autoimmune disease that causes inflammation across multiple organ systems, resulting in a wide range of clinical manifestations and ongoing challenges in disease management.[1,2] In autoimmune conditions such as lupus, the immune system produces autoantibodies that target healthy tissue, leading to inflammation, tissue injury, and organ damage.[2] The most common form, systemic lupus erythematosus (SLE), can affect the skin, joints, kidneys, brain, lungs, blood vessels, and other organs.[2]

Although advances have improved disease management, the etiology of lupus remains incompletely understood, and no cure exists.[1,2] Epidemiologic studies demonstrate variation in incidence, severity, and outcomes across populations. SLE occurs more frequently and with greater severity among Black, Hispanic/Latino, Asian, Pacific Islander, and American Indian, Alaska Native populations compared with non-Hispanic White populations.[3-6] Population-based registry data further show that these groups are more likely to experience earlier disease onset, higher disease activity, and increased risk of complications.[3–6] Women are disproportionately affected, particularly those of childbearing age.[2,6]

Clinical trials play a central role in the development of new lupus therapies. However, participation in lupus clinical trials does not consistently reflect the populations most affected by the disease. A recent systematic review of U.S. SLE clinical trials found underrepresentation of Black, Asian, and Hispanic/Latino participants across most included studies.[7] Earlier review literature similarly found that randomized SLE trials did not adequately reflect the racial and ethnic distribution of the lupus population.[8] This limits the ability to fully evaluate treatment effects across populations with the highest burden of disease.[7,8]

Barriers to clinical trial participation occur at multiple stages, including awareness, referral, enrollment, and retention. Lupus-specific studies have identified concerns about side effects, uncertainty about trial processes, limited awareness, and logistical challenges as key factors influencing participation.[9] In addition, broader clinical trial literature identifies factors across the patient journey that can affect recruitment and retention, including access barriers, trial burden, communication gaps, and site- or provider-level processes that influence whether patients move from outreach to enrollment.[10,11] These factors contribute to inefficiencies across the clinical trial pathway, particularly when research infrastructure is not well integrated with community-based care settings.[10,11]

Current implementation and community-engagement literature further support the value of trusted messengers and community-based partnerships in improving trial participation. A recent review on community engagement strategies for underrepresented populations emphasizes the importance of identifying strong community partners and addressing both patient- and provider-level barriers to participation.[12,13] A systematic review of strategies to improve enrollment of underrepresented populations found that successful approaches frequently used community-engaged methods and included health care providers as a key strategy.[12] Together, these findings support the use of trusted community channels and community-based partnerships to strengthen connections between outreach and enrollment.[11,12]

Despite continued efforts to improve participation, gaps in enrollment persist. Evidence suggests that these gaps are associated with limited access to trial-ready sites, insufficient alignment between outreach and enrollment processes, and barriers that affect both patients and providers.[6–12] Addressing these challenges requires coordinated approaches that strengthen community-based partnerships, improve pathway integration from awareness to enrollment, expand access to clinical trial infrastructure, and reduce operational barriers to participation.[7–12]

[illegible]. [illegible]pectations [illegible]or [illegible]ecipients

Funded projects should meet the following expectations:

a. Build and Sustain Trusted Community Partnerships

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

Recipients must have an established relationship with a lupus clinical trial site or have a plan to establish a relationship with a lupus clinical trial site by the end of the first quarter of the award period. In addition, recipients should implement a project that involves at least two collaborative partnerships with at least two different organizations. All partner organizations that will receive subawards of $10,000 or more must have an active SAM.gov registration at the time the application is submitted, or provide a written plan for obtaining registration within 30 days of award. For each anticipated subaward exceeding $10,000, the application must include a budget summary by object class, a description of the work to be performed, and the expected deliverables and timeline. Partners that are selected post-award must be documented in the first quarterly performance report with the same level of budget and scope detail. One of the organizations must be a:

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

We strongly encourage recipients to engage community-based organizations (CBOs), health care providers and clinical trial sites in their project implementation as appropriate. Recipients should demonstrate an existing partnership or a clear plan to establish relationships with lupus clinical trial sites to support referral, screening, enrollment, and retention activities.

b. Adaptation of Evidence-Informed Practice

We encourage recipients to adopt an evidence-informed practice to increase minority participation in clinical trials for the intended population of focus. We also expect recipients to implement the adapted intervention and ensure the sustainability of the improved results. Recipients should implement the adapted intervention(s) in underrepresented communities within cities and/or counties where lupus clinical trials are recruiting patients, and in medically underserved areas.

Interventions may include:

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

c. Demonstrate Increased Enrollment in Lupus Clinical Trials

We expect recipients to demonstrate the extent to which the project has increased the number of participants recruited, screened, and enrolled into lupus clinical trials. Recipients must establish a baseline count of referrals, screenings, and enrollments at the start of the project period, verified by the partnering clinical trial site(s), and must report against that baseline at each quarterly reporting interval. Self-reported enrollment counts must be corroborated by documentation from the clinical trial site (e.g., site enrollment logs, IRB-approved participant tracking records).

d. Implement a Process and Outcomes Evaluation

We expect projects to implement a rigorous evaluation to assess the impact of project activities. Recipients should implement a process and outcomes evaluation that assesses the extent to which the intervention increased underrepresented referrals, enrollment, and/or retention in lupus clinical trials. In addition to this measure, recipients should measure lupus clinical trial knowledge of healthcare providers/community health workers and measure attitudes, knowledge and beliefs gained using pre- and post-surveys. The evaluation should also assess the continued effectiveness of adapted interventions, fidelity, and any differential effects based on the adaptation approach.

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

Recipients should:

- Use SMART objectives
- Collect baseline, interim, and post-intervention data
- Measure outcomes across the participation pathway to ensure federal resources are impacting the number of referrals, enrollment and retention in lupus clinical trials

e. Document and Disseminate Project Findings

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

Recipients should:

- Publish findings
- Share best practices
- Ensure public accessibility

□. □ederal □nvolvement in the Pro□ect

If you receive an award, we will encourage you to seek the advice and opinion of federal staff when problems arise. However, you would be responsible for making sound programmatic and administrative judgments. The responsibility for operating decisions will be yours and does not shift to HHS, OASH, or OMH.

Under a grant, the program office's involvement may include routine monitoring and technical assistance such as monthly conference calls, occasional site visits, ongoing review of plans and progress, participation in relevant meetings, provision of training and technical assistance.

□. □ligibility criteria □or pro□ect participants

You must not restrict participation in the project on the basis of race, color, national origin, religion, sex, disability, age, or another protected characteristic (See Section H.5).

D. AWARD INFORMATION

Budget period

We expect to fund awards in 12-month budget periods for a total period of performance up to 36 months (3 years). However, we may approve shorter periods of performance. Budget periods may vary from the estimated 12 months because of the timing of award issuance or other administrative factors.

For multi-year projects, recipients must submit a non-competing continuation (NCC) application for each budget period after the first year. We will provide guidance generally 3 months prior to the end of the active budget period. Continuation funding is contingent upon the availability of funds, satisfactory progress of the project, appropriate stewardship of federal funds, and the best interests of the government. Funding for all approved budget periods after the first is generally the same as the initial award amount and may be subject to any offset with funds unused in a previous budget period.

E. APPLICATION CONTENTS AND FORMAT

□. □ormat o□ the Application

You must prepare your application using the forms and information described in this NOFO. The official online application package on Grants.gov contains all necessary forms and guidance for preparing an application. This package includes but is not limited to:

- Full Text of the NOFO
- Standard forms (required) and their instructions
  - SF-424 Application for Federal Assistance
  - SF-424A Budget Information for Non-Construction Programs
  - SF-LLL Disclosure of Lobbying Activities

- Project Abstract Summary

- Sample templates, if available.

In addition to the four standard forms in the application package, your application will consist of three sections of materials you prepare:

- Project Narrative
- Appendices to the Project Narrative
- Budget Package.

We strongly encourage you to read all instructions for the application format and content to avoid disqualification of your application. An application checklist is available in Section J.1.

a. Project Narrative – Formatting

Following the formatting instructions below will help ensure that your application is readable for review process. Acceptable electronic file formats are in Section E.3.a.

Names of Individuals

We encourage you to use individuals' full names (first, middle, last) on the standard forms and any other documents such as résumés/curricula vitae/biographical sketches to distinguish them for verification in the SAM exclusion records. Delays in award processing may result if full names are not provided.

You should avoid submitting personally identifiable information such as personal contact information (e.g., home address and telephone number) on résumés/curricula vitae/biographical sketches. Do not submit Social Security Numbers.

If you receive an award, only one Project Director/Principal Investigator (PD/PI) will be named on the award documents. (Section A.1.b) Avoid using a placeholder or honorary PD/PI. If you have not hired an individual to be the PD/PI, you should name an interim PD/PI, and your application should clearly identify that person as such.

We typically expect the PD/PI to be named on the SF-424 in box 8.f. Avoid naming grant writers in box 8.f unless they have the expertise to respond to technical questions about the proposed project in a timely manner.

Identify other personnel who are essential or key to the execution of the proposed project clearly in your project narrative.

If you receive an award, a request for a change in PD/PI or key personnel under any circumstance requires prior approval of the grants management officer before becoming effective. We may disallow any costs incurred as a result of that change prior to our approval. See Section H.1.c.

Page Formatting

If you submit documents that do not conform to the following instructions, GAM will disqualify your application during the review process (Section F.1.b).

Use an easily readable typeface, such as Times New Roman or Arial.

Use a 12-point font.

Use an 8.5” X 11” page size. Any other size page (e.g., A4, legal) will disqualify your application.

You must double-space the Project Narrative pages, or we will disqualify your application. You may single-space tables or use alternate fonts, but you must ensure the tables are easy to read.

Do not number pages or include a table of contents. Our grants management system will generate page numbers once your application is complete.

You must submit your application in the English language and in terms of U.S. dollars ([2 CFR 200.111](2 CFR 200.111)).

Page Limits

Your project narrative and appendices must adhere to these page limits.

The page limits do not include the budget package.

The page limits do not include the required forms (SF-424, SF-424A, SF-LLL, and the Project Abstract Summary).

If your application exceeds the specified page limits when printed on 8.5” X 11” page, we will not review your application further.

We encourage you to print out your application before submitting it to ensure that it is within the page limits and is easy to read. Do not reduce pages to fit multiple pages on a single sheet to avoid exceeding the page limitation.

Do not hyperlink to documents or sites outside of your application to augment your application. Reviewers will not be permitted to follow links to external content during their assessment of your application. The one exception to this is a link to your internal controls as part of your budget package.

	Page Limit
Project Narrative	40 pages
Project Narrative plus Appendices	65 pages

Labeling Proprietary Information

Proprietary information includes patentable ideas, trade secrets, privileged or confidential commercial or financial information, the disclosure of which may harm the applicant. You should include proprietary information in your application only to the extent that it is essential to the reviewers’ understanding of the project. Proprietary information should not appear in your Project Abstract Summary.

If your application contains proprietary information, you should clearly label the top of the first page of the project narrative. For example:

> "Contains proprietary or confidential information that [Your Organization Name] requests are not released to persons outside the government, except for purposes of review and evaluation."

Awarded applications are subject to release under the Freedom of Information Act (FOIA) with redactions as the FOIA statute permits.

b. Appendices to the Project Narrative – Formatting

Your appendices should include any specific items outlined in Section D.2.b. Your documents should be easy to read.

You should use the same formatting specified for the Project Narrative. However, documents such as résumés/curricula vitae/biographical sketches, organizational charts, tables, Memoranda of Agreement (MOAs) or Letters of Commitment (LOCs) may have formatting common to those documents, so long as the pages are easy to read. For example, resumes, MOAs and LOCs may be single-spaced.

You must upload all of your appendices as a single, consolidated file in the Attachments section of your Grants.gov application. You must use an acceptable file format (Section E.3.a). We strongly encourage you to convert your file(s) to PDF format before uploading and review them to ensure accurate conversion.

Your Project Narrative plus the Appendices may not exceed the total number of pages for the application (Section D.1.a).

c. Budget Package - Formatting

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 an 8.5" x 11" page. You must use an acceptable file format (Section E.3.a). We do not accept Excel or other similar spreadsheet formats.

The application page limit does not include the SF-424A or the budget narrative (including budget tables).

We recommend you present budget amounts and computations in a columnar format: first column, object class categories; second column, federal funds requested; third column, non-federal resources; and last column, total budget.

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

□. □ontent

a. Project Narrative - Content

The Project Narrative is the most important part of your application. We will use it as the primary basis to determine whether your project merits an award. The project narrative should provide a clear and concise description of your project. We recommend that your project narrative include the following components with the requested information. Labeling the sections accordingly will help the reviewers find information quickly.

- Significance of the Project;
- Goals, Objectives, and Outcomes;
- Project Plan;
- Organizational Capability;
- Evaluation Plan; and
- Dissemination Plan.

Further details:

Significance of the Project

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

Goals, Objectives, and Outcomes

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

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

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

Project Plan

In reference to your work plan in your appendices, provide a detailed summary of activities to be undertaken, and how those activities will assist in achieving the project goals and objectives including increasing underrepresented participation in lupus-related clinical trials. Explain the rationale for the lupus intervention you selected and present a clear connection between any identified evidence gaps, needs, and the proposed project activities. Describe how the intervention will be tailored for the population(s) of focus while maintaining fidelity to its core components. Also describe specific practices you will use in your project to address the contributing factor(s) your proposal addresses. Identify any major barriers anticipated and how the project will be able to overcome those barriers.

Describe the approach and rationale for recruiting, enrolling, and retaining participants. Also describe how the approach will increase the number of participants recruited, screened, and enrolled into lupus clinical trials. Describe how your project will increase provider and/or underrepresented participation and address barriers to underrepresented participation in lupus clinical trials.

Describe the proposed approach for developing public-private and community partnerships and related activities, and the rationale behind the strategies that will be used to work with partners to achieve the project goals.

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

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

Organizational Capacity

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

Describe how your organization (or your division of a larger agency responsible for this project) is organized, the nature and scope of its work, and the capabilities it possesses. Describe any current or previous relevant experience, including any significant experience relative to the inclusion of underrepresented populations in clinical trials. Describe any experience and expertise in the following area:

- Health education and outreach to of minority populations– including education on lupus disease awareness, health literacy, navigation of the healthcare system

- Clinical trial outreach to increase underrepresented population enrollment;
- Evaluation of outreach education and training programs related to recruitment, participation and retention in clinical trials; and
- Engagement with individuals and families of people living with lupus.

If relevant to your selected intervention, include experience working with CHWs and other patient advocates and their role in outreach, education, and training related to recruitment and participation in clinical trials.

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

Describe areas of expertise for key personnel in reference to the curricula vitae, résumés, or biographical sketches you submit. At a minimum, key personnel include the Program Director/Principal Investigator who will have day-to-day oversight of the project. You should identify the specific knowledge and expertise on issues related to clinical trials to support developing and implementing effective outreach or education interventions regarding lupus clinical trials. You should also identify the significant knowledge and expertise in lupus epidemiology, diagnosis, treatment, and health care access issues.

Key Personnel includes those individuals in roles who will oversee the technical, professional, managerial, and essential support functions and/or assume responsibility for assuring the validity and quality of your organization's project. Key personnel do not include individuals who provide routine administrative support to the project as part of their broader support of the organization. You should describe the qualifications, competing time commitments, and related ongoing projects of all key personnel. Identify the individuals/organizations responsible for evaluation activities and their qualifications. Describe the relationship between the evaluator and your organization and the degree of independence the evaluator will have. The evaluator must have structural independence from program implementation staff. Evaluators who report directly to the Project Director/Principal Investigator or who are responsible for implementing program activities are not considered independent. Recipients are strongly encouraged to contract with a third-party evaluator. If an internal evaluator is proposed, the applicant must provide a detailed explanation of the safeguards that will ensure objectivity, including separation of duties and independent reporting lines.

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

Evaluation Plan

Provide a process and outcomes evaluation plan for the project describing the evaluation approach you will use to determine whether the project reaches its population(s) of focus.

Your evaluation plan should demonstrate the impact of the project on the identified adverse health outcomes. Your evaluation design should clearly establish whether project activities result in the intended outcome(s). The evaluation design must demonstrate controls for threats to validity and the ability to show a statistically significant impact of your intervention on the key outcomes.

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

Include your approach to collecting, at minimum, baseline, interim, and post-intervention process and outcome measures.

Specifically describe how you will:

- Evaluate all components of the project's logic model, including how the inputs, processes, outputs, and outcomes will be measured and linked
- Track screening and enrollment outcomes, including eligibility determination and participation rates
- Monitor retention in clinical trials, where feasible, including follow-up mechanism
- Assess the extent to which the intervention(s) increased underrepresented participation across all stages of the clinical trial pathway (referral, screening, enrollment and retention)
- Identify barriers and challenges to participation in lupus clinical trials.
- Detail the role of your project partners in supporting data collection, tracking, and evaluation activities

Applicants must:

- Define measurable outcomes (not outputs)
- Demonstrate ability to detect impact
- Use quantitative and qualitative methods

Dissemination Plan

Describe the method you will use to disseminate the project's results and findings on time and in easily understandable formats to the population served, the general public, and other parties interested in using the project results. In addition to traditional forms of dissemination such as scholarly articles in peer review journals, we encourage you to propose innovative approaches to inform those who might be interested in using the results of your project. Dissemination efforts should focus on assisting those who may be interested in replicating your project. All relevant findings and products may be posted on an HHS/OMH- sponsored website as determined by HHS/OMH. See also Section F.9.

b. Appendices to the Project Narrative – Content

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.

Samples and optional forms/templates for some of these items are located under the Related Documents tab for this NOFO on Grants.gov.

Your application should include the following appendices:

Work Plan

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

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

Logic Model

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

Project Population(s) of Focus

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

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

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

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

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

Organizational Chart

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

Curriculum Vitae/Résumés/Biosketches for Key Project Personnel

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

References Cited

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

c. Budget Package - Content

A complete budget package consists of the following required components:

- SF-424A "Budget Information Non-Construction Programs"
- Budget narrative with detailed justification by cost category/object class, and
- Plan for oversight of federal funds.

You should include supporting documentation for your budget (e.g., a copy of your approved indirect cost rate) as part of the budget package, not as part of your appendices to the project narrative. There is no page limit for the budget package contents. If you are recommended for an award, you may be asked to provide additional information about your budget package.

Throughout your budget package, "Federal resources" refers only to the funds you are requesting from the program office for this project. "Non-federal resources" are all other non-HHS/OASH federal and non-federal resources. Funds from federal grant programs typically are not eligible as cost share for other federal grants. It is your responsibility to confirm with other federal agencies whether funds you receive from them are eligible resources to apply to your proposed project.

Standard Form SF-424A

You must enter the project budget according to the directions provided with the standard form.

You must provide costs by object class category for the first 12 months (i.e., first budget period) of the proposed project using Section B, box 6 of SF-424A. If the estimated period of performance is 12 months or less, this will be your total budget request for the entire project.

"Federal resources" refers only to the funds for which you are applying under this NOFO. "Non-federal resources" are all other resources (federal and non-federal).

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

If there is a discrepancy between your SF-424A and budget narrative and justification, we will rely on the narrative and justification to determine the final amounts.

Budget Narrative with Justification

Your budget narrative must include a detailed line-item budget and must include calculations for all costs and activities by the "object class categories" identified on SF-424A. You must provide a detailed justification for the costs by object class. The object class budget organizes your proposed costs into a set of defined categories.

Use the guidelines in Section J.4 for preparing the detailed object class budget.

Budget Periods

Your budget narrative must describe the first budget period in detail. For each proposed cost for the first budget period, provide a justification that includes explanatory text and line-item detail. You should describe how you derived your categorical costs. Your justification should show the necessity and reasonableness of the proposed costs for the project.

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

Funding levels for all approved budget periods after the first are generally the same as the initial award amount and are subject to an offset with funds unused in the previous budget period. Carryover of unobligated funds from one budget period to the next requires prior approval.

Determining Proposed Costs

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

Proposed costs must adhere to the cost principles described in 2 C.F.R. § 200.416. We have provided additional information on the most common cost categories for applications for OASH awards in Section J.4.

Budget calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient to verify the calculations. Carefully review Funding Restrictions (below) for specific information regarding allowable, unallowable, and restricted costs.

Describing Federal and Non-federal Share

Both federal and non-federal resources (if applicable) must be detailed and justified in the budget narrative. "Federal resources" refers only to the HHS/OASH funds for which you are applying under this NOFO. "Non-federal resources" are all other non-HHS/OASH federal and non-federal resources. If matching or cost sharing is required or offered voluntarily, you must include a detailed listing of any funding sources identified in box 18 of SF-424 (Application for Federal Assistance).

Indirect Costs

Indirect costs for training are limited to a fixed rate of eight percent of the modified total direct costs (MTDC) exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $50,000 (2 C.F.R. § 200.414 (c)(1)).

Funding Restrictions

The following restrictions apply to costs you may propose and be awarded.

Pre-Award Costs

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

Salary Rate Limitation

Each year's appropriations act limits the salary rate that you may charge to the grants and cooperative agreements that we award. You must not use 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 2026, the Executive Level II maximum salary is $228,000. 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:

Salary Rate Limitation	
Individual's *actual* base full-time salary $350,000 with 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
Individual's base full-time salary *adjusted* to Executive Level II: $225,700 with 50% of time devoted to the project	**Direct salary ($225,700 x 0.5)** = $112,850
	Fringe (25% of salary) = $28,212.50
	Total amount allowed = $141,062.50

Appropriate salary rate limits will apply as required by law.

Vehicle Purchase

We will not approve a vehicle purchase at the time of award even when included in your application. You must obtain prior approval before the purchase of a mobile health unit or any other vehicle with award funds. A request for prior approval must include a detailed justification of the need for the vehicle that includes an analysis of comparing purchase, lease, and other alternatives. Equipment purchases are subject to transfer to another federal project or sale at the end of the period of performance (2 C.F.R. § 200.313(e)).

Construction Costs

We will not approve construction costs. This includes major improvements to or significant renovations of facilities.

Plan for Recipient Oversight of Federal Award Funds

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

- how your organization will provide oversight of federal funds and how award activities and partner(s) will adhere to applicable federal award and programmatic regulations. Include identification of risks specific to your project as proposed and how your oversight plan addresses these risks.
- the organizational systems that demonstrate effective control over and accountability for federal funds and program income, compare outlays with budget amounts, and provide accounting records supported by source documentation.
- for any program incentives proposed, the specific internal controls that will be used to ensure only qualified participants will receive them and how they will be tracked. Incentive plans must include: (a) a per-participant cap on incentive value, justified in the budget narrative; (b) a unique participant identification system to prevent duplicate payments; (c) a reconciliation process comparing incentive disbursement records against clinical trial site screening and referral logs; and (d) a description of how incentive

- records will be made available for federal review upon request. Incentive structures that cannot be reconciled against independent site-level records will not be approved.
- 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 a link as part of your plan in the budget narrative. Although merit reviewers are not permitted to access any external materials linked in the application as part of their review, this link would facilitate review of your proposal if recommended for risk assessment (Section F.4).

Section J.5 contains questions you may find useful in preparing your Recipient Plans for Oversight of Federal Funds.

d. Project Abstract Summary Guidance

You must complete the Project Abstract Summary form. The application page limit does not include the Project Abstract Summary Form. Research projects may enter zero for “Estimated number of people to be served as a result of the award of this grant.”

The abstract will serve as the application summary going forward. Do not include sensitive or proprietary information in your abstract.

If your project is funded, we will publish the abstract on TAGGS.hhs.gov and USASpending.gov as you submitted it. You may request to edit it later, or we may ask you to edit it later to reflect any negotiated changes to the project. The abstract may also appear on the program office website or other government websites.

Your abstract should contain:

- Specifics about the project purpose
- Activities that you will perform
- Expected deliverables and outcomes
- Intended project beneficiary(ies) or participant(s)

Your description of the project should be brief and use plain language an average reader can understand. You should limit abbreviations, acronyms, or jargon without definitions. The abstract should be unique to your project.

E. SUBMISSION REQUIREMENTS AND DATES

1. Obtaining an Application Package

The official complete application package is available on Grants.gov. Search either the Assistance Listing number or the NOFO number MP-CPI-26-001.

The package consists of several Adobe PDF format documents. This is a standard format widely accessible across multiple platforms including mobile devices. The Acrobat Reader application is available at https://www.adobe.com/acrobat/pdf-reader.html.

All materials will be under the Package tab on the page for this opportunity on Grants.gov. If you have problems locating the application package, contact Grants.gov.

2. Required Registrations

You must have an active registration in SAM.gov and Grants.gov to apply for this opportunity.

It is your responsibility to plan ahead to ensure adequate time to register in both systems before submitting your application. We recommend beginning the registration process immediately, but **no later than** 30 days prior to the application deadline with a goal of your registration being complete at least 15 days prior to the application deadline.

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

Grants.gov will not accept an application unless you have an active SAM.gov registration and received a Unique Entity Identifier (UEI). There is no fee for registering in SAM.gov.

In cases where an individual is an eligible applicant (see Section A.1.a), the individual does not need a SAM.gov registration. However, the individual must still create a Grants.gov account. Grants.gov will assign a default UEI value where applicable.

We cannot make an award to your entity unless it has an active SAM registration. In accordance with 2 C.F.R. § 25.205, if you have not complied with this requirement, we may:

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

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

Registering in SAM

Your organization must register online in the System for Award Management (SAM). Grants.gov will reject submissions from applicants with nonexistent or expired SAM Registrations. You will find instructions on the Grants.gov website as part of the organization registration process.

Complete a SAM registration (or renewal) as soon as possible if you do not currently have an active registration that will remain active through the competitive process. Registration will include obtaining a unique entity identifier (UEI). SAM.gov provides an Entity Registration Checklist to help you prepare the necessary documentation.

You may register in SAM as an entity applying for either

- Federal Assistance Awards Only (e.g., grants and cooperative agreements) or
- All Awards (including procurement awards).

If you chose to register for All Awards, you must answer Yes to the question "Do you wish to apply for a federal financial assistance project or program, or is your entity currently the recipient of funding under any federal financial assistance project or program?" Failure to do so will require us to obtain a separate assurance document from you during our risk assessment (Section E.3) and may delay any award.

The list of representations and certifications to be certified as part of your registration is reproduced in Section J.6 with the corresponding HHS regulation citations. By submitting your application to this NOFO, your authorized representative certifies to these representations and certifications by signing Box 21 of SF-424A.

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 is the legal name and address we must use on the NOA.

During your registration, your organization will need to designate an E-Business Point of Contact (EBiz POC). The EBizPOC will need to be the individual to set up your Grants.gov account.

SAM Registration Renewal

If your organization has previously registered in SAM, confirm your status and determine whether you need to update or renew it. You must renew your SAM registration each year.

If you are successful and receive an award, you must maintain an active SAM registration with current information at all times during an active award or an application or plan under consideration by an HHS agency.

Timing of Registration

It may take up to 2-3 weeks (or longer during periods of high volume) for a registration to become active in SAM. After that, it may take an additional 24-72 hours for SAM to synchronize with Grants.gov. Grants.gov must recognize your SAM registration as active to accept your application. We strongly encourage confirming your registration status well before you are ready to submit your application to Grants.gov.

b. Grants.gov Registration

The Grants.gov Applicant Registration page provides the most up to date guidance on registering. There is no fee for registering to use Grants.gov.

Your EBizPOC may begin creating your account prior to receiving your UEI from SAM.gov. However, your will need to complete the SAM.gov registration prior to complete your Grants.gov registration.

Grants.gov is a platform that allows you to have multiple users with a variety of role-based access to perform actions on application(s). You must register an authorizing official for your organization. We do not determine who your organization's authorizing official is; your organization makes that decision. However, your authorizing official(s) must have the authority to act on behalf of your organization.

You may consider registering a backup authorized organization representative(s) in Grants.gov to ensure someone is available to submit your application. We will not extend due dates because your authorized official is unavailable.

We encourage potential applicants to familiarize themselves with the Workspace Overview and options as soon as possible.

□. □ubmission □nstructions

It is your responsibility to read and understand the instructions to submit a complete and properly formatted application.

a. Electronic Application Submission

We require that all applications be submitted electronically via Grants.gov unless the Grants Management Officer has granted an exemption in writing.

Grants.gov Information

You may access the application for this opportunity on Grants.gov. Search for the downloadable application page by the NOFO number MP-CPI-26-001 or Assistance Listing number 93.137, Community Programs to Improve Minority Health.

To ensure successful submission of your application, you should carefully follow the step-by-step instructions on the site. 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 technical system questions about the electronic application process (Section I).

See Section E.2 for requirements related to UEI numbers and SAM registration.

Electronic File Submission

Applications, excluding required standard forms, must be submitted as three (3) files. 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. Merit reviewers are not permitted to follow embedded links to materials outside of the application. Your content must fit within the page limits of the application.

File 1	The complete Project Narrative
File 2	All documents that make up the Appendices
File 3	The entire Budget Package including supporting documentation described in the Budget Narrative content section.

Acceptable File Formats

All files uploaded for your application must be in an acceptable file format and must contain a valid file format extension in the filename.

We only accept the file formats identified in the table to ensure compatibility across our other systems although Grants.gov will allow you to attach unacceptable formats.

We strongly encourage you to upload your application in Adobe PDF format. By converting to PDF prior to submission, you may prevent any unintentional changes that might occur with submission of an editable document. Most commonly available applications for document preparation have the ability to “Save As” or “Print To PDF.”

We do not recommend submitting scanned copies through Grants.gov unless you have confirmed the clarity of the scan and the readability of the documents.
Any file submitted as part of the Grants.gov application that is not in a file format listed as acceptable <u>will not be imported for processing</u> and <u>will be excluded from the application during the review</u>.

We will not contact you for resubmission of files to the correct the file type.

We will not contact you for passwords or for resubmission of unprotected files. We will forward unprotected information in the application forwarded for consideration, but we will not forward password protected portions.

Acceptable File Formats (extension)
• Adobe PDF (.pdf) • Microsoft Word (.doc or .docx) • Image formats (.jpg, .gif, .tif, or .bmp only)
Unacceptable File Formats (extension)
• Microsoft Excel files (.xls) or other similar spreadsheet files • Any compressed file formats (e.g., .zip, .rar, or Adobe Portfolio) • Any password protected files

Timing Considerations
We strongly encourage you to submit your application a minimum of 4-5 days prior to the application closing date. You are responsible for allowing time for system registrations and where applicable State Single Point of Contact (SPOC) notifications (Section E.3.d).

Do not wait until the last day in case you encounter technical difficulties, either on your end or with 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 accept 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. If you have reported a system problem to the Grants.gov helpdesk, obtain a ticket number to provide us so that we can verify the problem.

A “system problem” does not include known issues for which Grants.gov has posted instructions regarding how to submit an application successfully, such as compatible Adobe versions or file naming conventions. Nor does a “system problem” include issues that should have been identified by reviewing and confirming your account status prior to the submission deadline.

<u>Exemption to the Grants.gov Submission Requirement</u>
We will consider an exemption to the Grants.gov submission requirement only under limited circumstances. To obtain an exemption, you must request one via email from GAM at OASH-Grants-Feds@hhs.gov. Your request **must provide details as to why you are technologically**

unable to submit electronically through Grants.gov. You should submit your request at least 4 business days prior to the application deadline to ensure we can review your request at least to 2 business days before the deadline.

In your e-mail requesting an exemption include:

- the NOFO number;
- your organization's UEI number;
- your organization's name, address and telephone number;
- the name and telephone number of your Authorizing Official;
- the Grants.gov Tracking Number (e.g., GRANT####) assigned to your submission; and
- a copy of the "Rejected with Errors" notification from Grants.gov.

We will not grant an exemption to the electronic submission requirement for:

- Failure to have an active System for Account Management (SAM) registration prior to the application due date.
- Failure to follow Grants.gov instructions to ensure software compatibility.
- Failure to have the correct permission levels configured in your Grants.gov workspace.

GAM will only accept applications via alternate methods (i.e., PDF via email or hardcopy paper via U.S. mail or other provider) from applicants with prior written approval. If you receive an exemption, you must still submit your complete application, and we must receive it by the due date.

We will accept only applications submitted through Grants.gov or a pre-approved alternate format.

b. Submission Dates and Times

You must submit your application for this funding opportunity by July 10, 2026.

Your submission time is the date and time stamp provided by Grants.gov when you **complete** your submission. If you do not submit your application by the due date and time, we will not review it, and it will receive no further consideration.

It is your responsibility to review all instructions available on Grants.gov for successfully submitting an application. For information on registering for Grants.gov or to receive assistance on any technical system questions, contact Grants.gov directly (Section I).

c. NOFO Technical Assistance Webinar

We will provide a technical assistance webinar for applicants on June 24, 2026. The link to the recorded webinar will be posted at a later date to the documents tab on Grants.gov.

Applicants are encouraged to **subscribe to this opportunity on Grants.gov** to receive notification when the webinar link is posted, as well as any amendments, revisions, question and answer documents, or other updates.

Out for fairness to all applicants, we do not provide one-on-one consultation on the specific content development for any applications.

d. Intergovernmental Review

UPDATE FOR PROGRAM - This program is not subject to the Intergovernmental Review requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs," as implemented by 45 C.F.R. part 100.

□. Other Submission Requirements

a. Program-Specific Requirements

Non-profit Status

If you are a non-profit organization, you **may be required** to submit documentation of nonprofit status to confirm your status. Any of the following constitutes acceptable proof of such status:

- A reference to the Applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS code;
- A copy of a currently valid IRS tax exemption certificate;
- A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a nonprofit status and that none of the net earnings accrue to any private shareholders or individuals; or
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes nonprofit status.

b. Follow-up Submission Requirements

We may request additional documentation during the review process. We suggest having these documents readily available. Requests will only come from the OASH GAM staff. If you have any concern about the validity of a request, please contact us through the contact information provided in Section I.

Requested documentation may include a copy of your:

- Approved negotiated indirect cost rate, if not submitted in your budget package
- Internal controls
- Documentation of non-profit status
- Authorizing Tribal Resolution

We may request additional documentation as needed during our risk assessment process in Section F.4.

Failure to provide the requested documentation by the requested deadline may result in our no longer considering your application and moving on to another to make an award.

You should not interpret a request for information as an indication that we will make an award to you. A request only means that we are continuing to review your application.

F. APPLICATION REVIEW INFORMATION

Your application will undergo a series of reviews.

Application Qualification

GAM personnel will conduct a qualification review. There are three components to qualifying an application to proceed to merit review.

- **Eligibility Review** to determine whether you are an eligible applicant as described in Section A.
- **Responsiveness Review** to determine whether the responsiveness criteria have been met as described in Section F.1.
- **Formatting Review** to determine whether your application meets the formatting requirements described in Section D.1.

The Grants Management Officer will make the final determination on whether an application is eligible and qualified to proceed to merit review. This decision is not appealable.

Merit Review

An independent merit review panel will evaluate applications that are qualified and eligible. These reviewers are experts in their fields, and are drawn from academic institutions, non-profit organizations, state and local government, and Federal government agencies.

We do not disclose the identities of our review panelists. Each is vetted during the selection process to identify and manage any real or apparent conflict of interests.

Using the Merit Review Criteria, the reviewers will provide comments and rate the applications. We will provide reviewer comments to applicants after we have made final award decisions and issued notices of award. We do not provide scores.

Programmatic Technical Review and Risk Assessment

In addition to the independent merit review panel, federal staff will review each application for technical (programmatic), budgetary, and grants management compliance.

1. Responsiveness Review

The responsiveness review assesses your application at a high level to determine whether the application has addressed the subject matter of the opportunity or met any legal requirements. The criteria, if any, we describe below facilitate a go/no-go determination by the review team. Failure to address the responsiveness criteria clearly and provide the required information will result in disqualification.

a. Responsiveness Criteria

For this opportunity, the responsiveness criteria are:

The **Project Abstract Summary must**:

- **Clearly describe the focus of the proposed program**, including lupus awareness and education, and/or clinical trial education, outreach, and engagement strategies.
- **Identify at least two stages of the clinical trial participation continuum (awareness, referral, screening, enrollment, retention) that the project will address**
- **Specify the target population(s)and geographic area(s) of focus**, including populations disproportionately affected by lupus (e.g., racial/ethnic minorities, women of childbearing age, medically underserved or rural communities).
- Describe the primary intervention approach(es) (e.g., outreach, patient navigation, digital tools, site readiness) and how they will improve **clinical trial awareness and participation**, including strategies to address known barriers (e.g., mistrust, access, health literacy).
- **Indicate the role of partnerships**, such as with community-based organizations, healthcare providers, patient advocacy groups, or research institutions.
- Include at least two measurable outcomes related to clinical trial participation

b. Disqualifying Criteria
Disqualification means we will not review the application and will give it no further consideration.
We will disqualify applications:

• not submitted electronically via Grants.gov (unless an exemption was granted by the grants management officer in writing 2 business days prior to the deadline)
• not submitted by the due date and time (Section E.3.b)
• not submitted by an eligible applicant (Section A.1.a)
• submitted multiple times for the same project from the same organization, *except* for the last application received by the deadline (Section A.1.c)
• not meeting the Responsiveness Criteria (Section F.1.a), if any
• not including a non-federal sources justification in the budget narrative when including cost-sharing (voluntary or required) (Section A.3)
• requesting total funds (direct plus indirect costs) that are either: o Above the Award Ceiling of $500,000
• missing or incomplete required forms in the application package found on Grants.gov including SF-424; SF-424A, SF-LLL, and the Project Abstract Summary (Section D)
• not meeting the formatting requirements (Section D), specifically: o not submitted in the English language and U.S. dollars (2 CFR 200.111) o not submitted with ▪ an 8 ½ ” x 11” page size

- 1” margins on all sides (top, bottom, left and right)
- a font size of not less than 12 points
- a Project Narrative that is double-spaced

o exceeding the 40-page limit for the Project Narrative

o exceeding the total 65-page limit for the Project Narrative plus Appendices combined, excluding SF-424, SF-424A, SF-LLL, Project Abstract Summary, and Budget Narrative with budget tables

□. Merit □evie□ □riteria

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

a. Significance of the Project (10 points)

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

b. Goals, Objectives and Outcomes (15 Points)

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

c. Project Plan (25 points)

The project plan, including the work plan and activities described, will reasonably assist in the achievement of the stated project goals and objectives, including increasing underrepresented participation in lupus-related clinical trials. The lupus intervention selected for this project is clearly suitable to address any identified evidence gaps, needs, and the proposed project activities.

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

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

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

d. Organizational Capacity (20 points)

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

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

Additional Considerations

- Demonstrated ability to convert outreach to enrollment
- Strength of navigation model
- Capacity for site readiness
- Data tracking across participation pipeline

e. Evaluation Plan (20 Points)

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

The data identified for collection to be used to ensure the project activities are achieving their intended objectives and outcomes is reasonably appropriate and obtainable, including baseline, interim, and post-intervention process and outcome data. Any potential challenges to data collection are described with reasonable approaches to address them. The project's logic model, including how the inputs, processes, outputs, and outcomes will be measured, is rational and well-supported. Any involvement of partners in the evaluation activities is appropriate and beneficial to the overall evaluation. Applications proposing evaluators who lack structural independence from program implementation staff, or who fail to describe adequate safeguards for objectivity, will be scored lower on this criterion.

f. Dissemination Plan (10 Points)

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

□. Merit □evie□ and □election Process

Application Status Inquiries

During the review process, we do not release information about individual applications. If you would like to track your application, please see the instructions on Grants.gov.

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.

Federal Staff Review

In addition to the independent merit review panel, Federal staff will review each application for technical (programmatic), budgetary, and grants management compliance.

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

In providing these recommendations the program office will take into consideration the following additional factors(s):

- Geographic distribution

4. Review of Risk Posed by Applicant

Before issuing any award, GAM evaluates each recommended application for risks in accordance with 2 CFR 200.206. This evaluation may incorporate results of the evaluation for eligibility or of the quality of an application.

Risk Factors Considered

We will use a risk-based approach and may consider any items such as the following:

a. Your financial stability;
b. Quality of management systems and ability to meet the management standards prescribed in 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.

Also, prior to making a Federal award with a total Federal share greater than the simplified acquisition threshold (currently $250,000), GAM must review and consider any information about you that is in the designated integrity and performance system accessible through the System for Award Management (SAM) (formerly the Federal Awardee Performance and Integrity Information System (FAPIIS)).

If you are a prior Federal award recipient, the information in the system must, at a minimum, "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; see also 2 C.F.R. § 200.213. You have the option to review information in SAM and comment on any information about your organization that a Federal awarding agency previously entered and is currently available through SAM.

GAM 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.

Risk Review Outcomes

If GAM does not make an award to you because we determine that your organization does not meet either or both of the minimum qualification standards as described in 2 C.F.R. § 200.206, we must report that determination to FAPIIS, if certain conditions apply. See 2 C.F.R. § 200.213.

If GAM determines that a federal award will be made, specific 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. See 2 C.F.R. § 200.208.

H. AWARD NOTICES

Upon completion of risk analysis and concurrence of the GMO, GAM will issue Notices of Award (NOAs). No award decision is final until the GMO issues a NOA. All award decisions, including the level of funding, if an award is made, are final and you may not appeal.

We are not obligated to make any federal award as a result of this NOFO. If we make awards, the awards may be for periods shorter than indicated. Only the GMO can bind the federal government to the expenditure of funds.

Funded Applications

If you are successful, you will receive official notice of your award with a Notice of Award (NOA) via a system notification from our grants management system (Grant Solutions) and/or via e-mail. The NOA includes the amount awarded for the specified budget period, the purpose(s) of the award, the anticipated length of the period of performance, terms and conditions of the award, and the amount of cost share or matching, 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 (GMS) and Federal Project Officer (FPO) assigned to the award for assistance and monitoring. The GMS and FPO will work as a team. Any questions or concerns during the project should be communicated to both the GMS and FPO.

Pre-award costs are not allowed. If you begin a project prior to receiving a NOA or the project period start date on the NOA, you incur costs at your own risk. We will disallow the costs and will not approve them retroactively.

We intend to award funds as much in advance of the anticipated project start date (See Overview, page 1) 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.

Unfunded Applications

If you are unsuccessful or your application was disqualified, OASH will notify you by email and/or letter. If the merit review panel reviewed your application, you may receive summary comments pertaining to the application resulting from the review process. We do not release application scores.

You may receive a letter indicating that your application was "approved, but unfunded" (ABU). This does not mean you will receive an award or funding. Applications designated ABU are kept active for up to 12 months. During that time, a program office may consider an ABU application for award should funds become available. However, an ABU status does not guarantee that we will fund your project.

We will not transfer an ABU application for consideration under a new NOFO. You would have the option to resubmit your application, with any updated material, for consideration under that new NOFO.

I. AWARD REQUIREMENTS AND ADMINISTRATION

The following subsections describe the administrative requirements and the terms and conditions that will apply to any award you might receive under this NOFO.

As of October 1, 2025, HHS adopted 2 CFR Part 200, with some modifications included in 2 CFR Part 300. These regulations replace those in 45 CFR Part 75.

On October 2, 2024, HHS published an Interim Final Rule establishing a bifurcated transition to 2 C.F.R. part 200, the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. Under that transition, a few select provisions of 2 C.F.R. part 200 became effective October 1, 2024, while the remainder of provisions will become effective October 1, 2025, along with HHS-specific modifications to be codified at 2 C.F.R. part 300. Awards made under this NOFO will transition automatically to 2 C.F.R. part 200 effective October 1, 2025.

The regulatory citations below reference the currently applicable provisions of either 45 C.F.R. part 75 or 2 C.F.R. part 200.

1. Administrative and National Policy Requirements

a. Recipient Responsibilities

You will have full responsibility for the conduct of the approved project or activity and for adherence to all award terms and conditions, statutory, regulatory, or policy requirements applicable to grants and cooperative agreements. The approved project or activity is the project described in your application subject to any OASH GMO approved amendments. Approval of the project does not waive or negate any statutory, regulatory, or policy requirements applicable to grants and cooperative agreements.

You will be encouraged to seek the advice and opinion of the federal project officer and grants management specialist on special problems that may arise. Such advice does not diminish your responsibility for making sound programmatic and administrative judgments and does not imply that the responsibility for operating decisions has shifted to HHS, OASH, or the program office.

b. Accepting an Award

You accept an award and its terms and conditions by drawing or otherwise obtaining funds for the award from the grant payment system. By accepting an award, you agree to comply with the applicable federal requirements for grants and cooperative agreements, including those in the SAM registration certifications and representations, and to the prudent management of all expenditures and actions affecting the award, including the monitoring of any subrecipients.

You must comply with all terms, conditions, and requirements outlined in the Notice of Award, including: award policy terms and conditions contained in the HHS Grant Policy Statement (GPS), and its subsequent updates, all requirements imposed by program statutes and regulations, Executive Orders, and HHS grant administration regulations; and requirements or limitations in any applicable appropriations acts.

c. Scope of the Award and Prior Approvals

You may only use award funds to support activities in your funded project. HHS GPS Section II and 2 C.F.R. § 200.308 describe the aspects of your funded project that will require prior approval from the OASH GMO for any changes. Some of the award modifications to an approved project that will require prior GMO approval include:

- a change in the scope or the objective(s) of the project (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(s) specified in your application;
- reduction in time devoted to the project by the approved PD/PI, either as percentage of full-time equivalent of 25% or more or absence for 3 months or more; or
- the transferring of any work to another entity or individual through contract, subaward, or other means that differs from described in the awarded proposal.

d. Applicable Termination Provisions

If you receive an award, HHS may terminate it if any of the conditions in 2 C.F.R. §§ 200.340(a)(1)-(4) and 42 C.F.R. § 59.206(e) are met. No additional termination conditions apply, unless otherwise noted under Program Specific Terms and Conditions (Section F.3).

e. Alignment with Applicable Law

All activities proposed in your application and budget narrative must align with applicable law, including but not limited to statutes, executive orders, federal regulations, and applicable judicial holdings. Accordingly, discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate: racial preferences or other forms of racial discrimination by the recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation; denial by the recipient of the sex binary in humans, or the belief that sex is a chosen or mutable characteristic; illegal immigration; or any other initiatives that compromise public safety. If an application does not align, the application will not receive funding to the extent permitted by law and applicable court orders.

2. Program Specific Terms and Conditions

We may include on any awards made under this opportunity the following as special terms and requirements.

a. Paperwork Reduction Act Clearance Packages

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

3. Award Closeout

When the award expires, you must submit within 120 days all necessary documentation to closeout your award. If we do not receive acceptable final performance, financial, and property reports in a timely fashion and we determine that closeout cannot be completed with your cooperation, we must complete a unilateral closeout with the information available to us (2 C.F.R. § 200.344). See Section F.16 for specific detail.

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. As a result, we may also determine that enforcement actions are necessary, including actions such as withholding support or a high-risk designation on an existing or future award.

4. Lobbying Prohibitions

In general, any funds from an award made under this NOFO must not be used for other than normal and recognized executive legislative relationships. See 2 C.F.R. § 200.450.

You must 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
- 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 must not use any funds awarded 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.

5. Non-Discrimination Requirements

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

6. Smoke- and Tobacco-free Workplace

We strongly encourage 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 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 Organization Name.

You 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, Organization Name, OASH, HHS, or the U.S. Government. For more information, please visit [Organization Name website, if available].

8. HHS Rights to Materials and Data

All publications you develop or purchase with funds awarded under this announcement must adhere to the requirements of the program. You own the copyright for materials that you develop under an award, and pursuant to 2 C.F.R. § 200.315, the HHS awarding agency 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 2 C.F.R. § 200.315, 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 are subject to the requirements of Section 106(g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. § 7104).

10. Efficient Spending

Awards will 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.

11. Whistleblower Protection

Awards will include a term and condition that applies the terms of 2 C.F.R. § 200.217 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. Health Information Technology (IT) Interoperability

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

If you receive an award that involves:

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

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

13. 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.

14. Human Subjects Protection

Federal regulations (45 C.F.R part 46) require that applications and proposals involving human subjects be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in 45 C.F.R. part 46. Additional information is available on the Office of Human Research Protections website. This includes a series of decision charts to help assess whether an activity is human subjects research covered by the regulation and when an exemption may apply.

OASH requires, as part of any award involving human subjects, that recipients submit copies of all Institutional Review Board (IRB) approvals (not full protocols), or documentation of exemption determinations, within 5 days of the IRB approving the research or documentation of the specific exemption applied. Recipients must receive IRB approval or determine an exemption is applicable before any human subjects research begins.

15. Research Integrity

Federal regulations require that an applicant for or recipient of Public Health Service support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training must comply with the Public Health Service Policies on Research Misconduct in 42 C.F.R. part 93. Compliance includes having written policies and procedures for addressing allegations of research misconduct that meet the requirements of part 93, unless exempt; responding to each allegation of research misconduct for which the applicant or recipient is responsible under part 93 in a thorough, competent, objective, and fair manner; fostering a research environment that promotes the responsible conduct of research and discourages research misconduct; and maintaining an active assurance. More information about assurances is available in 42 C.F.R. Part 93 Subpart C and on the Office of Research Integrity assurance program website.

16. Reporting

Recipients must report on project progress (2 C.F.R. § 200.329) and financial status (2 C.F.R. § 200.328) during the course of the project. At the end of the project, acceptable final progress and financial reports are a requirement of the award closeout process. Failure to provide final progress or financial reports on any HHS award may affect decisions on future new or continuation funding.

a. Performance Project Reports (PPR)

Performance Project Reports (PPR)

You must submit periodic performance project reports on a quarterly basis via the Performance Project Report (PPR) module in GrantSolutions. We must receive the PPR by the due date included in the terms and conditions on the NOA. PPRs must address the content required by 2 C.F.R. § 200.329. The program office may provide additional guidance on the content of the progress report.

At the end of the project, you must submit a final performance report covering the entire period of performance no later than 120 days after the end of the period of performance. The program office may provide additional guidance on the content of the final report, which you must submit in the PPR module.

Project Performance and Continuation Awards

For projects with multiple budget periods anticipated, you will be required each year of the approved period of performance to submit in addition to your PPRs, a noncompeting continuation application. This application will include a summary of progress the last PPR, an updated work plan, and a budget package (SF-424A, narrative, and justification) for the upcoming budget period. Specific guidance will be provided via Grant Solutions well in advance of the application due date.

For the optional competitive additional year of funding intended to transition successful projects to sustainability, application guidance and review criteria will be provided during the final year of the period of performance.

We will award continuation funding based on availability of funds, satisfactory progress of the project, grants management compliance, including timely reporting, and continued best interests of the government. Progress is assessed relative to meeting the goals, objectives, and outcomes in the approved, funded project as described in the approved application and other supporting documents.

Performance Measures

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

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

- Progress toward approved project goals and objectives, including accomplishments, challenges, and lessons learned and progress on the evaluation plan
- Status of the project's staffing situation, including any changes affecting implementation
- The role and activities of each partner organization.
- Number and demographic characteristics of individuals reached (through outreach, education, and navigation activities)
- Types of outreach (method, audience, event type)
- Engagement of healthcare providers, community health workers, and other trusted messengers in training and capacity-building activities
- Progress across the clinical and clinical trial participation pathway, including:
    - Participant feedback
    - Number of referrals generated
    - Number screened

    - Number enrolled
    - Retention rates
- Dissemination of project activities, tools, and findings

b. Financial Reports

You must submit quarterly Federal Financial Reports (FFR) (SF-425). Your specific reporting schedule will be issued as a condition of award. Typically, we align the FFR reporting periods with the quarters of the federal fiscal year. FFRs are cumulative and due 30 days after the end of each reporting period or more specifically for the:

Quarter ending September 30, your FFR is due October 28
Quarter ending December 31, your FFR is due January 28
Quarter ending March 31, your FFR is due April 28
Quarter ending June 30, your FFR is due July 28.

In lieu of the last quarterly FFR, you will also be required to submit a final FFR covering the entire award 120 days after the end of the period of performance. You must submit FFRs via HHS Payment Management System (PMS) (https://pms.psc.gov).

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

c. Audits

If your organization expends $1,000,000 or greater in federal funds, it must undergo an independent audit in accordance with 2 C.F.R. § 200.501, often referred to as the Single Audit requirement.

d. 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 SAM.gov that is made available in the designated integrity and performance system (currently FAPIIS) about civil, criminal, or administrative proceedings described in paragraph A.2 of Appendix XII to **2 CFR part 200**. This is a statutory requirement (41 U.S.C. § 2313).

All information posted in the designated integrity and performance system will be publicly available. For more information about this reporting requirement related to recipient integrity and performance matters, see 2 CFR part 200, and the new 2 CFR part 300.

e. Other Required Notifications

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

- Are presently excluded or disqualified;

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

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

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

J. CONTACTS

Administrative and Budgetary Requirements

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

Eric West
OASH Grants and Acquisitions Management
Email: eric.west@hhs.gov

Program Requirements

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

CAPT Tarsha Cavanaugh
Office of Minority Health
Email: minorityhealth@hhs.gov

Grants.gov Support

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

GRANTS.GOV Applicant Support
Website: https://www.grants.gov
Phone: 1-800-518-4726
Email: support@grants.gov

SAM.gov Registration Support

For information or assistance on registering with SAM.gov, contact the General Services Administration (GSA) Federal Service Desk (FSD) Monday through Friday 8:00 AM to 8:00 PM Eastern at:

Website: https://www.fsd.gov/gsafsd_sp (Live Chat option available)
U.S. Phone: 866-606-8220
International Phone: +1 334-206-7828

K. OTHER INFORMATION

1. Application Checklist

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

Application Checklist	
	SAM.gov Registration/Renewal – start as soon as possible (recommended minimum of 6-8 weeks prior to submission deadline
	Grants.gov Registration (recommended minimum of 6-8 weeks prior to submission deadline)
	Application for Federal Assistance (SF-424)
	Budget Information for Non-construction Programs (SF-424A)
	Disclosure of Lobbying Activities (SF-LLL)
	Project Abstract Summary, including any responsiveness criteria (Section F.1.a)
	Project Narrative – Submit all Project Narrative content (Section D.2.a) as a single acceptable file (Section E.3.a).
	Project Narrative Appendices – Submit all Appendix content (Section D.2.b) as a single acceptable file (Section E.3.a).
	Budget Package – Submit all Budget Package content (Section D.2.c) as a single acceptable file (Section E.3.a). Note SF-424A is not included in the package and should be uploaded with the standard forms. Must include documentation of any cost-share or matching proposed regardless of whether it is voluntary or mandatory. (Section A.3)
	Other Submission Requirements (Section E.4).

□. Acronyms

ABU	Approved, but Unfunded
FFATA	Federal Financial Accountability and Transparency Act
FFR	Federal Financial Report (SF-425)
FSD	Federal Service Desk (GSA)
FSRS	FFATA Subaward Reporting System
GAM	Grants and Acquisitions Management Division
GMO	Grants Management Officer
GMS	Grants Management Specialist
GPS	Grants Policy Statement
GSA	General Services Administration
HHS	Department of Health and Human Services
IRB	Institutional Review Board
MDE	Minimum Detectable Effect
MTDC	Modified Total Direct Costs
NCC	Non-competing Continuation
NOA	Notice of Award
NOFO	Notice of Funding Opportunity
OASH	Office of the Assistant Secretary for Health
OMB	Office of Management and Budget
PD/PI	Project Director/Principal Investigator
PHS	Public Health Service
PPR	Performance Project Report
QED	Quasi-Experimental Designs
RCT	Randomized control trials
RDD	Regression discontinuity design
SF	Standard Form
SPOC	State Single Point of Contact

□. References

1. Fanouriakis A, Kostopoulou M, Andersen J, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. *Ann Rheum Dis.* 2024;83(1):15-29. doi:10.1136/ard-2023-224762.
2. Fava A, Petri M. Systemic lupus erythematosus: diagnosis and clinical management. *J Autoimmun*. 2019;96:1-13. doi:10.1016/j.jaut.2018.11.001.
3. Lim SS, Bayakly AR, Helmick CG, et al. The incidence and prevalence of systemic lupus erythematosus, 2002-2004: the Georgia Lupus Registry. *Arthritis Rheumatol.* 2014;66(2):357-368. doi:10.1002/art.38239.
4. Dall'Era M, Cisternas MG, Snipes K, et al. The incidence and prevalence of systemic lupus erythematosus in San Francisco County, California: the California Lupus Surveillance Project. *Arthritis Rheumatol.* 2017;69(10):1996-2005. doi:10.1002/art.40191.
5. Ferucci ED, Johnston JM, Gaddy JR, et al. Prevalence and incidence of systemic lupus erythematosus in a population-based registry of American Indian and Alaska Native people, 2007-2009. *Arthritis Rheumatol*. 2014;66(9):2494-2502. doi:10.1002/art.38720.
6. Barber MRW, Drenkard C, Falasinnu T, et al. Global epidemiology of systemic lupus erythematosus. *Nat Rev Rheumatol.* 2021;17(9):515-532. doi:10.1038/s41584-021-00668-1.
7. Sims S, Rowsey K, Hemmerich C, et al. Systematic review of inequitable population representation in systemic lupus erythematosus clinical trials. *Arthritis Care Res.* (Hoboken). 2025;77(11):1323-1331. doi:10.1002/acr.25576.
8. Falasinnu T, Chaichian Y, Bass MB, Simard JF. The representation of gender and race/ethnic groups in randomized clinical trials of individuals with systemic lupus erythematosus. *Curr Rheumatol Rep.* 2018;20(4):20. doi:10.1007/s11926-018-0728-2.
9. Arriens C, Aberle T, Carthen F, et al. Lupus patient decisions about clinical trial participation: a qualitative evaluation of perceptions, facilitators and barriers. *Lupus Sci Med.* 2020;7(1):e000360. doi:10.1136/lupus-2019-000360.
10. Dobra R, Wilson G, Matthews J, et al. A systematic review to identify and collate factors influencing patient journeys through clinical trials. *JRSM Open.* 2023;14(6):20542704231166621. doi:10.1177/20542704231166621.
11. Heller C, Balls-Berry JE, Nery JD, et al. Strategies addressing barriers to clinical trial enrollment of underrepresented populations: a systematic review. *Contemp Clin Trials.* 2014;39(2):169-182. doi:10.1016/j.cct.2014.08.004.
12. Odedina FT, Wieland ML, Barbel-Johnson K, Crook JM. Community engagement strategies for underrepresented racial and ethnic populations. *Mayo Clin Proc.* 2024;99(1):159-171. doi:10.1016/j.mayocp.2023.07.015.

□. Object Class Descriptions and Required Justifications

a. Personnel

Description

Includes costs of employee salaries and wages, excluding benefits.

Does NOT include consultants, subrecipient personnel costs, personnel costs outside of your organization. [2 C.F.R. § 200.459.]

Justification

Clearly identify the PD/PI, if known. 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 E.2.c.2).

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

b. Fringe Benefits

Description

Includes costs of personnel fringe benefits, unless treated as part of an approved indirect cost rate.

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.

c. Travel

Description

Includes costs of travel by staff of the applicant organization only.

Does NOT include travel costs for subrecipients or contractors under this object class.

Justification

For each trip proposed for your organization employees 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.

d. Equipment

Description

Includes tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost that equals or exceeds the lesser of the capitalization level established by the recipient or subrecipient for financial statement purposes, or $10,000 ((2 C.F.R. § 200.1 and § 200.313(e)).

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.

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; AND a plan for the use, and/or disposal of, the equipment after the project ends.

If your organization uses its own definition for equipment you should include in the budget narrative a copy of the policy, or section of your policy, that includes the equipment definition. Reference the policy in your justification. Do not include this policy in your appendices.

e. Supplies

Description

Includes 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 $10,000 (2 C.F.R. § 200.1).

Justification

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

f. Contractual

Description

Includes 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.

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 FAR 2.101 and currently set at $250,000. In some cases, OASH may require recipients make pre-award review and procurement documents, such as requests for proposals or invitations for bids, independent cost estimates, etc., available. Any proposal for awarding fixed amount subawards is subject to 2 C.F.R. § 200.333 and will require detailed justification to support the fixed award amount.

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

For subawards to community partner organizations central to program delivery, recipients must describe in the budget narrative the specific performance expectations for each partner, how partner performance will be monitored, and what corrective actions will be taken if a partner fails to meet agreed deliverables. This information should also be reflected in executed MOAs submitted as appendices.

g. Other

Description

Includes such costs as, where applicable and appropriate,

- 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.

Do not include costs covered by your negotiated indirect cost rate.

Justification

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

h. Indirect Costs

Description

Calculate your indirect costs based on a percentage of your modified total direct costs (MTDC)(2 C.F.R. § 200.1).

There are two methods. You must clearly identify the rate you used in your submitted budget.

Negotiated Indirect Cost Rate

If you have an approved negotiated indirect cost rate from the Department of Health and Human Services (HHS) or another cognizant federal agency, you should apply that negotiated rate. You should enclose a copy of the current approved rate agreement in your Budget package file.

> If you request a rate that is less than allowed, your authorized representative must submit a signed acknowledgement that you are accepting a lower rate than allowed. This should be an explicit statement that you are accepting a lower rate than is allowed and specify what the lower rate is.

De minimis Rate (2 C.F.R. § 200.414(f))

> If you do not have a current Federal negotiated indirect cost rate (including provisional rate) you "may elect to charge a de minimis rate of up to 15 percent of modified total direct costs (MTDC)." (2 C.F.R. § 200.414(f).) You may "determine the appropriate rate up to this limit. . . When applying the de minimis rate, costs must be consistently charged as either direct or indirect costs and may not be double charged or inconsistently charged as both." (2 C.F.R. § 200.414(f).) If you elect to use the de minimis rate, you must use the de minimis rate for all Federal awards until you choose to receive a negotiated rate.
>
> Indirect costs for training are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $50,000 (2 CFR 200.414).
>
> Modified Total Direct Cost (MTDC) means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and up to the first $50,000 of each subaward (regardless of the period of performance of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs, and the portion of each subaward in excess of $50,000. Other items may only be excluded when necessary to avoid a serious uneven distribution of indirect costs, and with the approval of the cognizant agency for indirect costs (2 C.F.R. § 200.1).

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.

i. Program Income

Description

Program income means gross income earned by your organization that is directly generated by an awarded project except as provided in 2 C.F.R. § 200.307. 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 2 C.F.R. § 200.307 and 35 U.S.C. § 200-212 (applies to inventions made under Federal awards).

Justification

Describe and estimate the sources and amounts of program income that this project may generate. All program income generated as a result of awarded funds must be used within the scope of the approved project-related activities.

Any program income earned must be used under the addition or additive method unless otherwise specified in Section C.2. These funds should not be added to your budget, unless you are using the funds as cost sharing or matching, if applicable. This amount should be reflected in box 7 of the SF-424A.

j. Non-Federal Resources (Cost Share or Match)

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 even if the justification exceeds the amount required.

For awards resulting from an application where you voluntarily propose cost sharing, we will include this voluntary cost sharing in the approved project budget, and you will be held accountable for it as shown in the Notice of Award (NOA).

Failure to meet a cost sharing or matching obligation that is part of the approved project budget on the NOA may result in the disallowance of federal funds.

If you are funded, you must report cost sharing or matching funds on your quarterly Federal Financial Reports.

Justification

You must provide detailed budget information in your budget narrative (not your appendices) for every funding source identified in box 18. "Estimated Funding ($)" on the SF-424.

You must fully identify and document the specific costs or contributions you propose as part of your required or voluntary cost sharing requirement. You must provide documentation in your application on the sources of funding or contribution(s).

For in-kind contributions, you must include how the stated valuation was determined. Matching or cost sharing must be documented by budget period.

Unrecovered indirect costs may be included as part of your cost sharing or matching only with prior approval of the grants management officer. Your budget narrative must clearly state that it is your intent to include unrecovered indirect costs as part of your cost sharing or matching. You should include in your budget narrative a copy of your negotiated cost rate to support the justification. Unrecovered indirect cost means the difference between the amount charged to the Federal award and the amount which could have been charged to the Federal award under your approved negotiated indirect cost rate. (See 2 C.F.R. § 200.306(c)).

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

□. Considerations in Recipient Plans for Oversight of Federal Funds

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

Questions for consideration in developing your plan may include:

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

- Supporting documents (e.g., purchase orders, Invoices, etc.) accompany checks submitted for signature and are marked "paid" or otherwise prominently noted after payments are made?

6. Financial Assistance General Certifications and Representations

When you register your organization in SAM.gov, you must complete the certifications and representations applicable to grants (i.e., federal assistance). We have provided for your reference the list of items that you are certifying when you complete this during your registration.

When your organization completes its registration (new or renewal) in SAM.gov, your organization attests that your organization:

1. Has the legal authority to apply for federal assistance and the institutional, managerial and financial capability to ensure proper planning, management, and completion of any financial assistance project covered by this Certifications and Representations document (See 2 C.F.R. § 200.113 Mandatory disclosures, 2 C.F.R. § 200.214 Suspension and debarment, OMB Guidance A- 129, "Policies for Federal Credit Programs and Non-Tax Receivables");
2. Will give the awarding agency, the Comptroller General of the United States and, if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives (See 2 C.F.R. § 200.302 Financial Management 2 C.F.R. § 200.303 Internal controls;
3. Will disclose in writing any potential conflict of interest to the federal awarding agency or pass through entity in accordance with applicable federal awarding agency policy (See 2 C.F.R. § 300.112 Conflict of interest;
4. Will comply with all limitations imposed by annual appropriation acts;
5. Will comply with the U.S. Constitution, all federal laws, and relevant Executive guidance in promoting the freedom of speech and religious liberty in the administration of federally-funded programs (See Statutory and national policy requirements [2 C.F.R. § 200.300]);
6. Will comply with all applicable requirements of all other federal laws, executive orders, regulations, and public policies governing financial assistance awards and any federal financial assistance project covered by this certification document, including but not limited to:
    1. Trafficking Victims Protection Act (TVPA) of 2000, as amended, 22 U.S.C. § 7104(g);
    2. Drug Free Workplace, 41 U.S.C. § 8103;
    3. Protection from Reprisal of Disclosure of Certain Information, 41 U.S.C. § 4712;
    4. National Environmental Policy Act of 1969, as amended, 42 U.S.C. § 4321 et seq;
    5. Universal Identifier and System for Award Management, 2 C.F.R. part 25;

6. Reporting Subaward and Executive Compensation Information, 2 C.F.R. part 170;OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Non-procurement), 2 C.F.R. part 180;
7. Civil Actions for False Claims Act, 31 U.S.C. § 3730;
8. False Claims Act, 31 U.S.C. §3729, 18 U.S.C. §§ 287 and 1001;
9. Program Fraud and Civil Remedies Act, 31 U.S.C. § 3801 et seq;
10. Lobbying Disclosure Act of 1995, 2 U.S.C. § 1601 et seq;
11. Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d et seq;
12. Title VIII of the Civil Rights Act of 1968, 42 U.S.C. § 3601 et seq;
13. Title IX of the Education Amendments of 1972, as amended; 20 U.S.C. § 1681 et seq
14. Section 504 of the Rehabilitation Act of 1973, as amended; 29 U.S.C. § 794; and
15. Age Discrimination Act of 1975, as amended, 42 U. S.C. § 6101 et seq.