

Centers for Disease Control and Prevention

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

Epidemiology of Lupus: Longitudinal Studies in Population-Based Cohorts

RFA-DP-22-002

Application Due Date will be submitted as: date based on the value specified for Due Date for Applications

Table of Contents

Section I. Funding Opportunity Description 4
Section II. Award Information....9
Section III. Eligibility Information 10
Section IV. Application and Submission Information....16
Section V. Application Review Information 26
Section VI. Award Administration Information 33
Section VII. Agency Contacts 45
Section VIII. Other Information 46

Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:
National Center for Chronic Disease Prevention and Health Promotion

Notice of Funding Opportunity (NOFO) Title

Epidemiology of Lupus: Longitudinal Studies in Population-Based Cohorts

Activity Code

Cooperative agreement: U01

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-22-002

Assistance Listings Number(s)

93.068

Category of Funding Activity

HL - Health

NOFO Purpose

The purpose of this funding opportunity is to better understand the epidemiology of lupus and improve understanding of how lupus impacts morbidity and mortality over time. To do that the applicants will need access to an existing adult or pediatric lupus population with a minimum of 5 years of follow-up for the adult population and 3 years of follow-up for the pediatric population. The study populations consist of (1) adults with diagnosed lupus aged 18 years or older, and (2) pediatric cases diagnosed with lupus aged <18 years.

The NOFO purpose will be accomplished through two components:

Component A: Epidemiology of Lupus Among Adults, using population registries to study adult lupus patients.
Component B: Epidemiology of Lupus in the Pediatric Population, using an existing cohort of pediatric lupus patients to study and advance existing knowledge of lupus in pediatric populations.

During the proposed 5-year funding period, it is anticipated that applicants for both Components A and B will carry out observational, longitudinal research of established, population-based cohorts in addition to collecting data for analysis and follow-up using a variety of proposed approaches such as recurrent surveys, personal contacts, medical examination, medical records, genetic analysis, and other laboratory testing.

Key Dates

Publication Date:

To receive notification of any changes to RFA-DP-22-002, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date:
12/20/2021
Publication Date: 11/05/21
LOI Date: 12/20/21

Application Due Date:
01/19/2022
1/19/2022

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 5:00 PM U.S. Eastern Time.

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission and prevents errors.

For more information on accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via http://grants.nih.gov/support/index.html.

- E-mail: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552.
  Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays.

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the application due date time to correct any error or warning notices of noncompliance with

application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review:
03/17/2022

Secondary Review:
05/11/2022

Estimated Start Date:
09/30/2022

Expiration Date:
01/20/2022

Required Application Instructions

It is critical that applicants follow the instructions in the How to Apply - Application Guide except where instructed to do otherwise in this NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Page Limitations: Pages that exceed the page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

Applications that do not comply with these instructions may be delayed or may not be accepted for review.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

Executive Summary

Purpose. The purpose of this funding opportunity is to better understand the epidemiology of lupus and improve understanding of how lupus impacts morbidity and mortality over time. Because lupus is a rare condition, applicants should already have access to an established, well characterized and on-going cohort of adults or youth with lupus of sufficient sample size for extrapolation to national estimates. Applicants will need existing access to an adult or pediatric lupus population with a minimum of 5 years of follow-up for the adult population and 3 years of follow-up for the pediatric population. The study populations consist of (1) adults with a lupus diagnosis aged 18 years or older and (2) children diagnosed with lupus aged 18 years or younger.
Mechanism of Support. Cooperative Agreement
Funds Available and Anticipated Number of Awards. The estimated total funding (direct and indirect) for the entire period of performance is $26,400,000 to support up to 6 awards. Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.
Budget and Period of Performance. Applicants are eligible to apply for both components A and B. For both components A and B, the estimated average award is $880,000, annually. The

estimated total funding (direct and indirect) for the first budget period (9/30/2022 to 9/29/2023) for Component A is $4,400,000 (5 awards) and for Component B is $880,000 (1 award). The estimated total funding (direct and indirect) for the entire Period of Performance (9/30/2022 to 9/29/2027) for Component A is $22,000,000 (5 awards) and for Component B is $4,400,000 (1 award).
Application Research Strategy Length: Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.
Eligible Institutions/Organizations. Institutions/organizations listed in Section III.1 are eligible to apply.
Eligible Project Directors/Principal Investigators (PDs/PIs). Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
Number of PDs/PIs. Applications may include more than one PD/PI; however, the first PD/PI listed on the application will be the contact PI for all correspondence. Additional PIs are permitted; but they will be referred to as Co-PIs.
Number of Applications. One application per eligible institution (normally identified by having a unique DUNS number) is allowed for each Component. Separate applications are required for each Component.
Application Type. New
Special Date(s). None
Application Materials. See **Section IV.1** for application materials.
Hearing Impaired. Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.

A link to this NOFO on Grants.gov is available at https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm

Section I. Funding Opportunity Description

Statutory Authority

This program is authorized under 317(k) (2) of the Public Health Service Act (PHS Act), 42 U.S.C. 247b(k)(2) and 301(a) of the PHS Act, 42 U.S.C. 241(a).

1. Background and Purpose

Lupus is an autoimmune disease with a wide spectrum of illness that can affect almost any tissue and organ in the body and cause severe morbidity and premature mortality. Systemic lupus erythematous (SLE) is the most common and serious form of lupus. Recent estimates suggest that around 200,000 US adults have SLE though prior estimates ranged as high as 1.5 million. Disparities in SLE incidence and prevalence are noted, affecting women far more than men and minorities more than whites. The causes of SLE are unknown but likely linked to genetic, environmental, and hormonal factors. Data regarding SLE in pediatric populations are very limited, and Congress directed CDC to continue working with existing childhood lupus registries to generate more robust information about the impact of the disease in children in the FY21 Appropriations Act.

There is continued need for a basic epidemiologic understanding of lupus to elucidate the full

clinical spectrum and population impact of the disease. CDC has funded adult population-based registries up to 18 years, and pediatric population-based registries for over 2 years, from a diverse geographic distribution across the United States allowing for epidemiological estimates to not only be generalizable to the United States, but also to different unique and underserved populations with varying degrees of lupus burden. A pediatric registry was added in the last funding period (CDC-RFA-DP19-003). A wealth of information is emerging from these registries, but more is needed to understand the epidemiology of lupus to inform public health action. Published studies include the first population-based estimates of lupus incidence and prevalence in whites, blacks, Hispanics, Asians, American Indians/Alaska Natives, Arabs, and Chaldeans, but estimates for other groups have yet to be obtained.[1-6] Previous registry research has found that 1 in 3 adults with lupus use prescription opioids and have lower adherence to prescription medications and lower health care access than controls.[7] More research is needed to understand why this is happening. Furthermore, lower socioeconomic status has been shown to be associated with more severe lupus outcomes and lower adherence to lupus medication.[8,9] Additional research can help identify what can be done to lower these risk factors for poorer outcomes in lower SES lupus populations.

This NOFO will support research designed to better understand the epidemiology of lupus by determining treatment patterns and impacts, health care access, disparities, and long-term natural history (severity, morbidity, mortality) of lupus (systemic lupus erythematosus). This observational, longitudinal research will solicit established, population-based cohorts to collect data over 5 years using a variety of methods such as recurrent surveys, personal contacts, medical examination, medical records, genetic analysis as well as analysis of existing longitudinal data. Up to five adult population registries (Component A: Epidemiology of Lupus Among Adults) and one pediatric registry (Component B: Epidemiology of Lupus in the Pediatric Population) will be funded.

Extended follow up of long-term cohorts will allow data collection that adds unique knowledge and insight into the epidemiology of lupus and its impacts on morbidity and mortality, such as the contributions of genetic and social factors as well as patterns of care in lupus outcomes, and transitions to adulthood and continuity of care.

Healthy People 2030 and other National Strategic Priorities

Analyses from this NOFO address all four arthritis Healthy People 2030 objectives on doctor-diagnosed arthritis because lupus is included in the definition of doctor-diagnosed arthritis, which includes more than 100 different conditions. The four arthritis objectives are A-01 (moderate or severe joint pain), A-02 (activity limitations), A-03 (work limitations), and A-04 (counseling for physical activity). These objectives are available at https://health.gov/healthypeople the Healthy People 2030 website.[10]

Public Health Impact

The results from this study will provide a better understanding of the epidemiology, clinical patterns, treatment of the disease, and lupus-related morbidity and mortality. This research addresses a public health gap by advancing epidemiologic understanding of lupus, a disease that is difficult to diagnose; confirming the burden and outcomes of lupus; and providing direction for the interventions to address identified lupus and lupus comorbidities. With this information, clinical and public health approaches can be enhanced to help improve the quality of life and

health outcomes of adults with lupus. Findings will be used to target interventions, inform best practices, improve health equity among populations heavily impacted by lupus, and educate providers, researchers, and patients.

Relevant Work
CDC has funded population-based lupus registries for up to 18 years with an earlier focus on incidence/prevalence of lupus. The current NOFO (CDC-RFA-DP19-003) funds 4 adult lupus registries at the University of Michigan, University of Utah, Emory University, and the University of California San Francisco. A pediatric registry was added in the current NOFO (Epidemiology of Lupus: Longitudinal Studies in Population-Based Cohorts, CDC-RFA-DP19-003).

2. Approach

The NOFO has two components. Component A: Epidemiology of Lupus Among Adults is intended to support applicants with access to an existing adult lupus patient population and at least 5 years of follow-up from baseline. Component B: Epidemiology of Lupus in the Pediatric Population is aimed at supporting a pediatric registry with at least 3 years of follow-up from baseline to extend existing knowledge of lupus in pediatric populations. Because lupus is a rare condition, it is efficient to obtain new information from existing lupus cohorts to reduce costs and recruitment times, except where new lupus population cohorts may be warranted to answer new scientific or public health questions. In any longitudinal cohort study the greatest new knowledge and value comes from continued follow-up. Further, longer-term follow-up of an existing lupus cohort is critical to achieving the objectives of epidemiologic research and addressing current gaps in the literature on lupus and longitudinal outcomes such as quality of life, disability, and mortality. Numerous longitudinal studies of other chronic diseases demonstrate that longer-term follow-up of specific people with the disease provides greater understanding of disease natural history as well as clinical and treatment features impacting quality of life and medical management of disease.

During the proposed 5-year funding period, it is anticipated that applicants for both Components A and B will carry out observational, longitudinal research of established, population-based cohorts in addition to collecting data for follow-up using a variety of proposed approaches such as recurrent surveys, personal contacts, medical examination, medical records, genetic analysis, and other laboratory testing. While earlier CDC funding periods focused on incidence and prevalence, the focus of this NOFO is on collection of data related to the course of lupus and its consequences for people with lupus (e.g., function, quality of life, disability, and mortality). Topics of consideration for data collection and/or data analysis may include but are not limited to disease severity; genetic linkages; health care practices; social, behavioral, and psychosocial factors; laboratory markers, and others suggested by applicants. Because of reliance on existing registries, extending prior information for longitudinal studies and new information collection will both be beneficial.

Applicants may apply for Component A and/or Component B. Separate applications are required for each Component.

Objectives/Outcomes
Component A: Epidemiology of Lupus Among Adults

Outcomes and Objectives

- Examine the treatment (e.g., medications including opioid; type; appropriateness; etc.) of people with lupus.
- Determine health care access and gaps that people with lupus experience in addressing their varied health problems (e.g., general health problems as well as those for specific lupus outcomes, such as nephritis; transition from pediatric to adult healthcare for people diagnosed as children).
- Determine longer term natural history (severity, chronic pain, progression, morbidity, mortality, disability and quality of life, work/ school/activity interference, etc.) of people with lupus, including assessing potential genetic factors.
- Examine other factors related to disparities in lupus outcomes (e.g., age, sex, race/ethnic group, and socioeconomic status).
- Examine lupus comorbidities.
- Translate findings to influence public health practice via the dissemination of findings for education, outreach and awareness to scientific researchers, clinical practitioners, and the affected population.

Component B: Epidemiology of Lupus in the Pediatric Population

Outcomes and Objectives

- Examine the treatment (e.g., medications including opioid; type; appropriateness; etc.) of people with lupus.
- Determine health care access and gaps that people with lupus experience in addressing their varied health problems (e.g., general health problems as well as those for specific lupus outcomes, such as nephritis; transition from pediatric to adult healthcare for people diagnosed as children).
- Determine longer term natural history (severity, chronic pain, progression, morbidity, mortality, disability and quality of life, work/ school/activity interference, etc.) of people with lupus, including assessing potential genetic factors.
- Examine other factors related to disparities in lupus outcomes (e.g., age, sex, race/ethnic group, and socioeconomic status).
- Examine lupus comorbidities.
- Translate findings to influence public health practice via the dissemination of findings for education, outreach and awareness to scientific researchers, clinical practitioners, and the affected population. Findings should be documented through presentations and peer-reviewed publications and any media should be documented as well. Findings should be disseminated to deliver education and awareness to appropriate target audiences, including providers, care givers, and people living with lupus.

Target Population

Component A: Epidemiology of Lupus Among Adults: Applicants are expected to target adults (≥18 years) impacted by lupus, identified from an existing and ongoing registry, and followed up for at least 5-years. The study population chosen should be as representative of the US population as possible and include ethnic/racial minorities, urban/rural populations,

individuals of low socioeconomic status, those with disabilities, and sexual and gender minority populations. The results from the study population chosen should be extrapolated to the entire US population, so the study design must be capable of generating national estimates.

Component B: Epidemiology of Lupus in the Pediatric Population: The target population includes pediatric patients (aged <18 years) impacted by lupus, identified from a registry, and followed up for at least 3-years. The study population chosen should be as representative of the US pediatric population as possible and include ethnic/racial minorities, urban/rural populations, individuals of low socioeconomic status, those with disabilities, and sexual and gender minority populations. The results from the study population chosen should be extrapolated to the entire US population, so the study design must be amenable to generating national estimates.

Collaboration/Partnerships

Component A: Epidemiology of Lupus Among Adults and Component B: Epidemiology of Lupus in the Pediatric Population

Applicants are expected to collaborate with stakeholders that will promote increased lupus education, outreach, and provider and patient awareness. Furthermore, collaborating with outside subject matter experts in the field of lupus epidemiology is encouraged. Finally, collaborations with organizations focused on social determinants of health, health equity, and health disparities is highly encouraged.

Evaluation/Performance Measurement

The awardees are expected to develop an evaluation plan by the 6th month post award. This plan should align with the stated purpose and outcomes of the NOFO, which includes participant follow-up, and progress towards meeting study objectives. Evaluation plan should be used to monitor data collection, analysis, and publication status of proposed research articles. Recipient should specify details related to scale, staffing, or resources in the evaluation plan. Evaluation plans can be refined with CDC post-award. Specific information regarding evaluation can be found at: https://www.cdc.gov/eval/index.htm

Translation Plan

For both Component A: Epidemiology of Lupus Among Adults and Component B: Epidemiology of Lupus in the Pediatric Population, the funded applicants are expected to include a plan for translation of the findings to influence public health practice and disseminate findings for education, outreach and awareness to scientific researchers, clinical practitioners, and the affected population.

OMB/PRA is not expected to apply.

References

1. Somers EC, Marder W, Cagnoli P, et al. Population-based incidence and prevalence of systemic lupus erythematosus: the Michigan Lupus Epidemiology and Surveillance Program. *Arthritis Rheumatol*. 2014;66(2):369–378. doi: 10.1002/art.38238. PubMed:24504809.
2. Lim SS, Bayakly AR, Helmick CG, Gordon C, Easley KA, Drenkard C. 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. PubMed: 24504808.
3. 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):2492-2502. doi: 10.1002/art.38720.PubMed: 24891315.
4. Housey M, Deguire P, Lyon-callo S, et al. Incidence and prevalence of systemic lupus erythematosus among Arab and Chaldean Americans in southeastern Michigan: the Michigan Lupus Epidemiology and Surveillance Program. *Am J Public Health*. 2015;105(5):e74-9. doi: 10.2105/AJPH.2014.302423. PubMed: 25790387.
5. Izmirly PM, Wan I, Sahl S, et al. The incidence and prevalence of systemic lupus erythematosus in New York County (Manhattan), New York: The Manhattan Lupus Surveillance Program. *Arthritis Rheumatol*. 2017;69(10):2006-2017. doi: 10.1002/art.40192.
6. 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.
7. Somers EC, Lee J, Hassett AL, Zick SM, Harlow SD, Helmick CG, Barbour KE, Gordon C, Brummett CM, Minhas D, Padda A, Wang L, McCune WJ, Marder W. Prescription opioid use in patients with and without systemic lupus erythematosus—Michigan Lupus Epidemiology and Surveillance Program 2014-2015. *Morb Mortal Wkly Rep.* 2019;68(38):819-824.
8. Courtney Hoge; C. Barrett Bowling, S. Sam Lim, Cristina Drenkard, and Laura Plantinga. Association of Poverty Income Ratio with Physical Functioning in a Cohort of Patients with Systemic Lupus Erythematosus. J Rheumatol. 2020 Jul 1; 47 (7):983:990
9. DeQuattro K, Trupin L, Li J, Katz PP, Murphy LB, Yelin EH, Rush S, Lanata C, Criswell LA, Dall'Era M, Yazdany J. Relationships Between Adverse Childhood Experiences and Health Status in Systemic Lupus Erythematosus. Arthritis Care Res (Hoboken). 2020 Apr; 72 (4): 525-533.
10. Healthy People 2030 Arthritis Objectives: https//healthypeople/objectives-and-data/browse-objectives/arthritis

3. Funding Strategy

N/A

Section II. Award Information

Funding Instrument Type:
CA (Cooperative Agreement)
A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed:
New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

Estimated Total Funding:
$26,400,000
Estimated total funding (direct and indirect) for the first budget period (9/30/2022 to 9/29/2023)

- Component A: $4,400,000

- Component B: $880,000

Estimated total funding (direct and indirect) for the period of performance (9/30/2022 to 9/29/2027)

- Component A is $22,000,000
- Component B is $4,400,000

The award ceiling for both Components A and B is $900,000

Anticipated Number of Awards:
6
Component A : 5 awards (average award amount per budget period $880,000)
Component B: 1 award (average award amount per budget period $880,000)

Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling:
$900,000
Per Budget Period

Award Floor:
$870,000
Per Budget Period

Total Period of Performance Length:
5 year(s)

Throughout the Period of Performance, CDC's commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and CDC's determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this NOFO.
If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR Part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
20 (Private institutions of higher education)

04 (Special district governments)

22 (For profit organizations other than small businesses)

08 (Public housing authorities/Indian housing authorities)

99 (Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility")

00 (State governments)

07 (Native American tribal governments (Federally recognized))

02 (City or township governments)

01 (County governments)

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

23 (Small businesses)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

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

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

Additional Eligibility Category:

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Institutions of Higher Education:

Hispanic-serving Institutions

Historically Black Colleges and Universities (HBCUs)

Tribally Controlled Colleges and Universities (TCCUs)

Alaska Native and Native Hawaiian Serving Institutions

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government

U.S. Territory or Possession

Other:

Faith-based or Community-based Organizations

Regional Organizations

Foreign Organizations: a Foreign Organization is a public or private organization, whether non-profit or for-profit, located in a country other than the United States (U.S.) and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance.

Bona Fide Agents: A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms."

Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to https://gov.ecfr.io/cgi-bin/searchECFR.

2. Foreign Organizations

Foreign Organizations **are not** eligible to apply.

Foreign components of U.S. Organizations are not eligible to apply.

For this announcement, applicants may not include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Additional Information on Eligibility

Special Eligibility. For an application to be considered, the application must be responsive to these Special Eligibility Requirements. If your application is incomplete or non-responsive to the special eligibility requirements listed in this section, it will not enter into the review process.

Component A: Epidemiology of Lupus Among the Adults

- Applicants must have access to an existing and established baseline cohort of lupus patients that has been followed for at least 5 years.
- The sample size of the cohort to be used for this study should include a minimum of 400 lupus participants.
- If an applicant requests a funding amount greater than the ceiling of $900,000 (Section II. Award Information) for either Component (A or B) as indicated in Section II of this NOFO, HHS/CDC will consider the application non-responsive, and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirement.

Component B: Epidemiology of Lupus in the Pediatric Population

- Applicants must have access to an existing and established baseline cohort of lupus patients that has been followed for at least 3 years.
- The sample size of the cohort to be used for this study should include a minimum of 400 lupus participants.
- If an applicant requests a funding amount greater than the ceiling of $900,000 (Section II. Award Information) for either Component (A or B) as indicated in Section II of this NOFO, HHS/CDC will consider the application non-responsive, and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirement.

4. Justification for Less than Maximum Competition

NA

5. Responsiveness

If the Responsiveness information requested below is incomplete or non-responsive to these requirements, the application will not enter into the review process.

Component A: Epidemiology of Lupus Among in the Adults

- Evidence of access to an established cohort followed for at least 5 years - Applicants must provide a letter of support, memorandum of agreement, or other required documentation showing this. This documentation should be placed in Appendix A of the application.
- Evidence of at least 400 lupus patients in the cohort study - Applicants must provide a letter of support, memorandum of agreement, or other required documentation showing this. This documentation should be placed in Appendix A of the application.

Component B: Epidemiology of Lupus in the Pediatric Population

- Evidence of access to an established cohort followed for at least 3 years - Applicants must provide a letter of support, memorandum of agreement, or other required documentation showing this. This documentation should be placed in Appendix A of the application.
- Evidence of at least 400 lupus patients in the cohort study - Applicants must provide a letter of support, memorandum of agreement, or other required documentation showing this. This documentation should be placed in Appendix A of the application.

Ceiling - If an applicant requests a funding amount greater than the ceiling for Component A ($900,000) and Component B ($900,000), HHS/CDC will consider the application non-responsive and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

PLEASE NOTE: For applications due on or after January 25, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. Grant application forms and instructions will be updated to reflect and require UEI instead of DUNS. If already registered in SAM.gov, a UEI was automatically generated for your entity and is visible in both SAM.gov and Grants.gov. Entities registering in SAM.gov prior to April 2022 must still obtain a DUNS number before registering in SAM and a UEI will be assigned during SAM.gov registration.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato.int/AC135Public/Docs/US Instructions for NSPA NCAGE.pdf
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, SAM.gov.
- Grants.gov
- eRA Commons

All applicant organizations must register with Grants.gov. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The one-time registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Senior/Key Personnel (including Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principal Investigator (PD/PI) eRA Commons account is affiliated with the eRA commons account of the applicant organization. All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have an active eRA Commons account in order to prepare an application. It also requires that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission, therefore the applicant organization must ensure that their Grants.gov AOR credentials are active.

7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants

or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

PLEASE NOTE: For applications due on or after January 25, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. Grant application forms and instructions will be updated to reflect and require UEI instead of DUNS. If already registered in SAM.gov, a UEI was automatically generated for your entity and is visible in both SAM.gov and Grants.gov. Entities registering in SAM.gov prior to April 2022 must still obtain a DUNS number before registering in SAM and a UEI will be assigned during SAM.gov registration.

Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at SAM.gov and the SAM.gov Knowledge Base.

If an award is granted, the recipient organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the recipient organization.

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

9. Cost Sharing

This NOFO does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement,(https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), applications received in response to the same Notice of Funding Opportunity generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this NOFO that is essentially the same as one currently

pending initial peer review unless the applicant withdraws the pending application.

One application per eligible institution (normally identified by having a unique DUNS number) is allowed for each Component. Separate applications are required for each Component.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because, unlike other platforms, it provides a validation of all requirements prior to submission and prevents errors.

To use ASSIST, applicants must visit https://public.era.nih.gov where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process.

If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via: http://grants.nih.gov/support/index.html

- Email: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552.
  Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays.

2. Content and Form of Application Submission

Applicants must use FORMS-G application packages for due dates on or after January 25, 2022 and must use FORMS-F application packages for due dates on or before January 24, 2022.

Application guides for FORMS-G application packages will be posted to the How to Apply - Application Guide page no later than October 25, 2021.

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide How to Apply - Application Guide except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.

When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

Please use the form and instructions for SF424 (R&R) Form F. Applicants must use FORMS-F application packages for due dates on or before January 24, 2022.

3. Letter of Intent

Due Date for Letter Of Intent 12/20/2021

12/20/2021
Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information it contains allows CDC staff to plan for the review.
By December 20, 2021, prospective applicants are asked to submit a letter of intent that includes the following information:

- Name of the Institution
- Descriptive title of proposed research, including Component
- Name, address, and telephone number of the PD(s)/PI(s)
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

The letter should be emailed to:

Sue Shaw, MPH
Scientific Program Official
Telephone: 770.488.6142
Email: researchnofo@cdc.gov
Note: Include NOFO number in the email subject line.

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this NOFO in Grants.gov includes all applicable components for this NOFO, required and optional. In ASSIST, all required and optional forms will appear as separate tabs at the top of the Application Information screen.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide at How to Apply - Application Guide for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. **Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the NOFO.
2. **Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.

3. **Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and time line.
4. **Progress Report Publication List** (for Continuation ONLY)

Other Research Plan Sections

5. **Vertebrate Animals**
6. **Select Agent Research**
7. **Multiple PD/PI Leadership Plan.**
8. **Consortium/Contractual Arrangements**
9. **Letters of Support**
10. **Resource Sharing Plan(s)**
11. **Authentication of Key Biological and/or Chemical Resources**
12. **Appendix**

All instructions in the SF424 (R&R) Application Guide at How to Apply - Application Guide must be followed along with any additional instructions provided in the NOFO.

Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.

The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and deidentified data).

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx)

Other examples of DMPs may be found here: USGS, http://www.usgs.gov//products/data-and-tools/data-management/data-management-plans

Applicants must use FORMS-G application packages for due dates on or after January 25, 2022 and must use FORMS-F application packages for due dates on or before January 24, 2022.

Application guides for FORMS-G application packages will be posted to the How to Apply - Application Guide page no later than October 25, 2021.

Research Plan

- Applicants may apply for Component A: Epidemiology of Lupus Among Adults **and/or** Component B: Epidemiology of Lupus in the Pediatric Population.
- The application should clearly indicate the name of the Component (Component A: Epidemiology of Lupus Among Adults **or** Component B: Epidemiology of Lupus in the Pediatric Population).
- A separate application must be submitted for each Component.
- Use form and instructions for SF424 (R&R) Form F. Applicants must use FORMS-F application packages for due dates on or before January 24, 2022.

The following research plan components are applicable for both Component A: Epidemiology of Lupus Among Adults and Component B: Epidemiology of Lupus in the Pediatric Population:

The applicant's research plan should address activities that will be performed over the entire performance period and should include the following items:

1. Describe the existing prospective cohort study (e.g., duration of follow-up, location) and the outcomes to be achieved.
2. Describe sampling plan to demonstrate how obtained estimates from a sufficient sample size will be extrapolated and generalized to the US population.
3. Describe the proposed study population (e.g., age, sex, race).
4. Describe the proposed data collection methods (e.g., over the phone, mail, in-person).
5. Describe the variables, in alignment with the NOFO purpose, and how they are measured using self-reports or other methods such as those used to examine sociodemographic patterns, healthcare access, quality of life, chronic conditions, or mortality.
6. Describe the process of recruiting participants, their follow-up and data collection frequency over the five-year funding period. Also describe how often participants are contacted for each visit.
7. Describe the proposed analytic or statistical methods for all study objectives. Describe the statistical tests and software to be used.
8. Describe proposed major analytic studies to be carried out during the funding period.

Management and Staffing Plan

1. Describe the proposed management and staffing plan of the study. Include a staffing plan that describes the roles and percentage of time on the project.
2. Describe plans for maintaining project activities when staff vacancies occur.
3. Describe experience and expertise of proposed staff, including their ability to manage this study. Include a description of the staff experience with data collection, managing data, follow-up of participants, using appropriate analytic methods. What experience do they have collecting lupus-related data?
4. Describe plans for ensuring that program maintains local IRB approval and new key personnel, or other significant contributors involved in the design or conduct of research involving human subjects meet educational program requirement in the protection of human subjects.

Translation Plan

1. Include a plan for translation of the findings to influence public health practice and disseminate findings for education, outreach and awareness to scientific researchers, clinical practitioners, and the affected population.
2. Describe how you plan to document findings through presentations and publications, as well as communication products for the affected patient population and providers.

Collaboration

1. Describe plans for developing/expanding collaborations with stakeholders that can work to promote increased lupus medical and public health education, outreach, and awareness.

    - Describe specific roles and responsibilities for grantee and stakeholder.

2. Describe plans for collaborating with outside subject matter experts in the field of lupus epidemiology.

6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publicly available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 30 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers

and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide at .How to Apply - Application Guide.

Applicants must use FORMS-G application packages for due dates on or after January 25, 2022 and must use FORMS-F application packages for due dates on or before January 24, 2022.

Application guides for FORMS-G application packages will be posted to the How to Apply - Application Guide page no later than October 25, 2021.

Please use the form and instructions for SF424 (R&R) Form F. Applicants must use FORMS-F application packages for due dates on or before January 24, 2022.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes. Applicants will use a platform or system to submit applications.

ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission. If ASSIST detects errors, then the applicant must correct errors before their application can be submitted. Applicants should view their applications in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application must be resubmitted in ASSIST.

Applicants are able to access, view, and track the status of their applications in the eRA Commons.

Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at https://era.nih.gov/files/ASSIST_user_guide.pdf.

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on Federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/web/grants/support.html
support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

It is important that applicants complete the application submission process well in advance of the due date time.

After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor agency has confirmed receipt of the application.

Unsuccessful Submissions: If an application submission was unsuccessful, the **applicant** must:

1. Track submission and verify the submission status (tracking should be done initially regardless of rejection or success).

    a. If the status states "rejected," be sure to save time stamped, documented rejection notices, and do #2a or #2b

2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.

    b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications 01/19/2022

01/19/2022
Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Funding Restrictions

Expanded Authority:

For more information on expanded authority and pre-award costs, go to https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf and speak to your GMS.

All HHS/CDC awards are subject to the federal regulations, in 45 CFR Part 75, terms and conditions, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

Public Health Data:

CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards.

Data Management Plan:

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.

Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).

Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: https://www.cdc.gov/grants/additional-requirements/ar-25.html

Human Subjects:

Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions.

If the proposed research project involves more than one institution and will be conducted in the United States, awardees are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and include a single IRB plan in the application, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy or a compelling justification based on ethical or human subjects protection issues or other well-justified reasons is provided. Exceptions will be reviewed and approved by CDC in accordance with Department of Health and Human Services (DHHS) Regulations (45 CFR Part 46), or a restriction may be placed on the award. For more information, please contact the scientific/research contact included on this NOFO.

Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in CDC-funded, cooperative research studies are not expected to follow the requirement for sIRB.

Funds will be restricted until:

- IRB and OMB/PRA (if needed) approvals are obtained. IRB approval letters must be dated and should specify the name of the NOFO, or title of the project covered and the expiration date or lack of need for continuation review. If and when new supplements are added to the protocol, dated IRB approval letters for protocol amendments are required.

If the amendment approval letter does not specify the content of the amendment, a summary of the amendment request that was submitted to the IRB is required.

- Awardee organizations that rely on other institutions for their IRB review responsibilities shall provide documentation of the reliance and the IRB approval.

11. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e., grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding

source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

Report Submission: The applicant must upload the report under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

Application Submission

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_ redirect.htm? id=11144).

Important reminders:
All Senior/Key Personnel (including any Program Directors/Principal Investigators (PD/PIs) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.

It is also important to note that for multi-project applications, this requirement also applies to the individual components of the application and not to just the Overall component.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

PLEASE NOTE: For applications due on or after January 25, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. Grant application forms and instructions will be updated to reflect and require UEI instead of DUNS. If already registered in SAM.gov, a UEI was automatically generated for your

entity and is visible in both SAM.gov and Grants.gov. Entities registering in SAM.gov prior to April 2022 must still obtain a DUNS number before registering in SAM and a UEI will be assigned during SAM.gov registration.

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications:

- http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm
- http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm
- https://era.nih.gov/files/ASSIST_user_guide.pdf
- http://era.nih.gov/erahelp/ASSIST/

Upon receipt, applications will be evaluated for completeness by the CDC Office of Grants Services (OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.d/////

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (http:// www.cdc.gov/ about/ organization/ mission.htm), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

For Components A and B:

- If successful, will the research results be translatable to the entire US population?
- Will the proposed lupus research lead others to investigate the problem, open new areas of research, or change the scientific or public health approach to lupus?
- Are the research questions relevant and may translate to public health action?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

For Components A and B:

- Does the applicant adequately document the experience of project leadership and their ability to achieve project aims related to lupus epidemiology and public health practice?
- Are the PD/PIs, collaborators, and other researchers well suited to perform lupus epidemiological research and translate lupus epidemiological findings to address lupus public health issues?
- Has the project leadership demonstrated an ongoing record of accomplishments in the field of lupus epidemiology and public health practice?
- Do the applicants have a successful track record in public health research (e.g., evidence of epidemiological research that resulted that has applied public health implications)?
- Does the applicant have evidence of past collaborations in lupus epidemiology and public health practice?
- Does the applicant have evidence of lupus epidemiological research that has contributed to improvements in public health practice and population health?
- To what extent does the applicant provide a reasonable and appropriate staffing plan including a description of staff contributions, roles, and time for lupus activities?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

For Components A and B:

- To what extent does the applicant propose methods to address the epidemiological lupus study objectives that are innovative?
- Does the application challenge and seek to shift current public health practice paradigms or approaches in regard to lupus epidemiology and public health practice?

- Is the applicant's approach to addressing lupus epidemiology and public health practice innovative, but also offer reasonable potential for concrete applications of interest and value to the CDC?
- Does the proposed project have the potential to lead to cost savings in regard to lupus epidemiology and public health practice (i.e., applied public health)?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

For Components A and B:

- Is the applicant's overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of this project?
- Is the proposed project strategy feasible?
- Does the application describe how the results from the research will be disseminated and ultimately used for public health practice?
- Is the proposed dissemination plan adequate?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

For Components A and B:

- To what extent does the applicant's scientific environment in which the work will be done contribute to the probability of success?
- Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
- Will the applicant's project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
- Does the applicant's project utilize critical partnerships or collaborations?

2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (https://www.cdc.gov/grants/additionalrequirements/ar-1.html).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children
When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (https://www.cdc.gov/maso/Policy/Policy_women.pdf and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/maso/Policy/policy496.pdf).

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following four points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 4) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VAChecklist.pdf).

Biohazards
Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Dual Use Research of Concern
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of

Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dualuse/Pages/companion-guide.aspx.

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations

N/A

Resource Sharing Plan(s)

HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html

New additional requirement: CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.

Investigators responding to this Notice of Funding Opportunity should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.

The DMP should include, at a minimum, a description of the following:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and de-identified data).

Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx

Other examples of DMPs may be found here USGS, http://www.usgs.gov//products/data-and-tools/data-management/data-management-plans

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html

The budget can include both direct costs and indirect costs as allowed.

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.

If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

4. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.
As part of the scientific peer review, all applications:

- Will undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office.
Applications will compete for available funds with all other recommended applications

submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding recommendations:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance with 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC’s framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is 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;
(4) Reports and findings from audits performed under 45 CFR Part 75, subpart F, or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this NOFO will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

PLEASE NOTE: For applications due on or after January 25, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. Grant application forms and instructions will be updated to reflect and require UEI instead of DUNS. If already registered in SAM.gov, a UEI was automatically generated for your entity and is visible in both SAM.gov and Grants.gov. Entities registering in SAM.gov prior to April 2022 must still obtain a DUNS number before registering in SAM and a UEI will be assigned during SAM.gov registration.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the grantee's business official.

Recipient must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants

Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: http://www.access.gpo.gov/nara/cfr/cfr-table- search.html.

Specific requirements that apply to this NOFO are the following:

ARs relevant to NOFO:

AR-1: Human Subjects Requirements

AR-2: Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2030

AR-12: Lobbying Restrictions

AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-21: Small, Minority, And Women-owned Business

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

AR-27: Conference Disclaimer and Use of Logos

AR-28: Inclusion of Persons Under the Age of 21 in Research

AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009

AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973

AR-31: Research Definition

AR-32: Appropriations Act, General Provisions

AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AR-36: Certificates of Confidentiality

AR-37: Prohibition on certain telecommunications and surveillance services or equipment for all awards issued on or after August 13, 2020.

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

AR 23: Compliance with 45 C.F.R. Part 87

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy).This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy applies to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at: https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single,

publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

Plain Writing Act The Plain Writing Act of 2010, Public Law 111-274, was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: http://www.plainlanguage.gov/plLaw/index.cfm.

Pilot Program for Enhancement of Employee Whistleblower Protections All applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however, the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

> The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

Language Access for Persons with Limited English Proficiency Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

Dual Use Research of Concern On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC, involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.

Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG-funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG-funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG-funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

Data Management Plan(s)

CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.

This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo).

The AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

Certificates of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of

Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC-supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at: https://www.cdc.gov/grants/additionalrequirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

The PD(s)/PI(s) will have the primary responsibility for:

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Nonresearch Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html ;

Additional PI responsibilities include:

- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.
- Providing oversight of the management and administrative aspects of the project, including maintaining an adequate staffing plan to support project activities.

CDC's role is to provide technical and scientific advice where needed, but that the recipient has final decision making on the project, data collection and approach. CDC's role is to assist the investigators in achieving the study objectives as stated.

- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Nonresearch Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

Additional CDC staff responsibilities include:

- Provide scientific and technical assistance as needed to assist the investigators in achieving the study objectives
- Contribute to analyses, publications, and other products on request
- Facilitate distribution and dissemination of research findings

Recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies. Additionally, an agency program official or CIO Program Official will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice. The SPO will be:

• Named in the Notice of Grant Award (NGA) as the Program Official to provide oversight and assure overall scientific and programmatic stewardship of the award;
• Monitor performance against approved project objectives; and
• Assure assessment of the public health impact of the research conducted under this funding opportunity announcement and promote translation of promising practices, programs, interventions, and other results from the research.

Areas of Joint Responsibility include:

- Attending monthly/quarterly CDC and awardee technical call to update CDC on project progress and for CDC to provide guidance to the grantee
- Meeting biannually to perform a site visit at the awardee host site to evaluate project progress made by the awardee. Site visits may also occur at CDC program site.

5. Reporting

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually
(see https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/forms/report_on_grant.htm) and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:
1) Information on executive compensation when not already reported through the SAM Registration; and
2) Similar information on all sub-awards/ subcontracts/ consortiums over $25,000. It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A. Submission of Reports

The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report**, is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
2. **Annual Federal Financial Report (FFR) SF 425** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the period of performance.**

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress should include:

    - Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
    - Research Aims: list each research aim/project

a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned

b) Leadership/Partnership: list project collaborations and describe the role of external partners.

    - Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet,

this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. Questions to consider in preparing this section include:

- How will the scientific findings be translated into public health practice or inform public health policy?
- How will the project improve or effect the translation of research findings into public health practice or inform policy?
- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
- How will the findings advance or guide future research efforts or related activities?

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. Questions to consider in preparing this section include:
- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations contribute to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.

- New Budget Period Proposal:
- Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
- Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."

- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project's data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

Certification that any new key personnel or other significant contributors involved in the design or conduct of research involving human subjects have completed an educational program in the protection of human subjects.

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through the Payment Management System (PMS) within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.

The due date for final FFRs is 90 days after the Period of Performance end date.

Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.

Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https://commons.era.nih.gov/commons/ for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: https://era.nih.gov/docs/Commons_UserGuide.pdf.

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the Period of Performance. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.
- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC-funded activity. Please include any additional dissemination efforts that did or will result from the project.
- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;

(2) By the HHS awarding agency or pass-through entity for cause;

(3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

(4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

7. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) (“United States foreign assistance funds”). Outlined below are the specifics of this requirement:

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be

submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:

"Commodity" means any material, article, supplies, goods, or equipment;

"Foreign government" includes any foreign government entity;

"Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:

a. recipient name;

b. contact name with phone, fax, and e-mail;

c. agreement number(s) if reporting by agreement(s);

d. reporting period;

e. amount of foreign taxes assessed by each foreign government;

f. amount of any foreign taxes reimbursed by each foreign government;

g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

Scientific/Research Contact

Sue Shaw, MPH

Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
Telephone: 770.488.6142
Email: researchnofo@cdc.gov
Note: Include NOFO number in the email subject line when submitting questions.

Peer Review Contact
Jaya Raman, PhD
Scientific Review Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
Telephone: 770.488.6511
Email: kva5@cdc.gov

Financial/Grants Management Contact
Angie N. Willard
Grants Management Specialist
CDC Office of Grants Services
Telephone: 770.488.2863
Email: aen4@cdc.gov

Section VIII. Other Information

Other CDC Notices of Funding Opportunities can be found at www.grants.gov.

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations
Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code of Federal Regulations.

Awards are made under the authorization of 317(k) (2) of the Public Health Service Act (PHS Act), 42 U.S.C. 247b(k)(2) and 301(a) of the PHS Act, 42 U.S.C. 241(a)