Centers for Disease Control

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office

Epidemiology of Lupus: Longitudinal Studies in Population-Based Cohorts
RFA-DP-19-003
Application Due Date: 03/08/2019

Epidemiology of Lupus: Longitudinal Studies in Population-Based Cohorts
RFA-DP-19-003
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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control

Components of Participating Organizations

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office (NCCDPHP ERPO)
National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)

Notice of Funding Opportunity (NOFO) Title

Epidemiology of Lupus: Longitudinal Studies in Population-Based Cohorts

Activity Code

U01

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-19-003

Assistance Listings (CFDA) Number(s)

93.283

Category of Funding Activity:

Health

NOFO Purpose

This NOFO is intended to support research on lupus through a 2-component cooperative agreement:

Component A (Longitudinal Studies of Lupus in Population-based Cohorts of Adults with Lupus: 3 Year Followup):

This is a longitudinal followup study designed to support an established, US-based, population-based cohort of adults age 18 and older with diagnosed lupus (systemic lupus erythematosus {SLE} and skin lupus) that includes followup data collected at least once since 2015**.** The intent of this study is to conduct data collection, building upon the cohort and initial followup activities. This data collection should include four content areas:

1. The natural history (e.g., severity, morbidity, mortality, disability, comorbidity, work interference, etc.) of cohort members, and
2. Treatment (e.g., medications, therapy, self-management, etc.) of lupus including the treatment of chronic pain and opioid use, and
3. Health care access and gaps that adults with lupus experience, and
4. Disparities (e.g., age, race/ethnicity, sex) and other factors associated with lupus outcomes.

Component B: (A Pediatric Lupus Registry with Longitudinal Followup):

This is a project that will support an existing US-based registry of children age 0-17 years with diagnosed lupus (SLE and skin lupus). The intent of this study is to gather baseline for children

age 0-17 years and followup data for this cohort for three additional years. The baseline and followup data should include these 4 content areas:

1. The natural history (e.g., severity, morbidity, mortality, disability, comorbidity, work interference, etc.) of cohort members, and
2. Treatment (e.g., medications, therapy, self-management, etc.) of lupus including the treatment of chronic pain and opioid use, and
3. Health care access and gaps that children with lupus experience, and
4. Disparities (e.g., age, race/ethnicity, sex) and other factors associated with lupus outcomes.

Key Dates

Publication Date:	**To receive notification of any changes to RFA-DP-19-003, 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:	**02/08/2019**
Application Due Date:	**03/08/2019**

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. Applications must be submitted using the Application Submission System & Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore identifying issues earlier in the application submission process.

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:	**04/18/2019**
Secondary Review:	**05/19/2019**

Estimated Start Date:	**09/01/2019**
Expiration Date:	**03/09/2019**
Due Dates for E.O. 12372:	**Executive Order 12372 does not apply to this program.**

Required Application Instructions

ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review). Use of the Grants.gov downloadable Adobe application packages and submission process will still be supported.

It is critical that applicants follow the instructions in the SF 424 (R&R) 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.

Note: The Research Strategy component of the Research Plan is limited to 25 pages.

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

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

Executive Summary

1. Purpose. This NOFO is intended to support research on lupus through a 2-component cooperative agreement:

Component A (Longitudinal Studies in Population-based Cohorts of Adults with Lupus: 3 Year Followup):

This is a longitudinal followup study designed to follow an established, US-based, population-based cohort of adults age 18 and older with diagnosed lupus (systemic lupus erythematosus {SLE} and skin lupus) that includes followup data collected at least once since 2015**.** The intent of this study is to conduct data collection, building upon the cohort and initial followup activities. This data collection should include four content areas:

1. The natural history (e.g., severity, morbidity, mortality, disability, comorbidity, work interference, etc.) of cohort members, and
2. Treatment (e.g., medications, therapy, self-management, etc.) of lupus including the treatment of chronic pain and opioid use, and
3. Health care access and gaps that adults with lupus experience, and

4. Disparities (e.g., age, race/ethnicity, sex) and other factors associated with lupus outcomes.

Component B (A Pediatric Lupus Registry with Longitudinal Followup):

This is a project that will support an existing US-based registry of children age 0-17 years with diagnosed lupus (SLE and skin lupus). The intent of this study is to gather baseline data for children age 0-17 years and follow up data for this cohort for three additional years. The baseline and follow up data should include these 4 content areas:

1. The natural history (e.g., severity, morbidity, mortality, disability, comorbidity, work interference, etc.) of cohort members, and
2. Treatment (e.g., medications, therapy, self-management, etc.) of lupus including the treatment of chronic pain and opioid use, and
3. Health care access and gaps that children with lupus experience, and
4. Disparities (e.g., age, race/ethnicity, sex) and other factors associated with lupus outcomes.

Applicants can apply for Component A, Component B or both but there must be separate applications if applying for both.

2. Mechanism of Support. Cooperative Agreement

3. Funds Available and Anticipated Number of 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.

- Component A: 9/1/19 - 8/31/20, is $2,700,000 for 3 awards. The average award amount is $900,000 per award in year one.The estimated total funding (direct and indirect) for the entire period of performance, 9/1/19 - 8/31/22, is $8,100,000 for 3 awards.
- Component B: 9/1/19 - 8/31/20, is $800,000 for 1 award. The estimated total funding (direct and indirect) for the entire period of performance, 9/1/19 - 8/31/22, is $2,400,000.

4. Budget and Period of Performance. The estimated total funding (direct and indirect) for the first budget period:

- Component A: The estimated total funding (direct and indirect) for the entire period of performance is $8,100,000, to fund up to 3 awards. Average award will be $2,700,000 at $900,000 per year per award.
- Component B: The estimated total funding (direct and indirect) for the entire period of performance is $2,400,000, to fund 1 award at $800,000 per year.

5. Application Research Strategy Length: Page limits for the Research Strategy are specified in Section IV. Application and Submission Information of this announcement.

6. Eligible Institutions/Organizations. Institutions/organizations listed in Section III, 1.A. are eligible to apply.

7. 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.

8. Number of PDs/PIs. Applications may include more than one PI; however, the first PI listed on the application will be the ?contact PI? for all correspondence. Any additional PIs are permitted, but would be referred to as Co-PIs.

9. Number of Applications Only one application per institution (normally identified by having a unique DUNS number) is allowed.

10. Application Type. New.

11. Special Date(s). Not applicable.

12. Application Materials. See Section IV.1 for application materials. Please note that Form E is to be used when downloading the application package

13. Hearing Impaired. Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.

A link to this NOFO will be available at Notice of Funding Opportunities | Our Programs | National Center for Chronic Disease Prevention and Health Promotion | CDC

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Section 301(a) of the Public Health Service, 42 U.S.C. 241(a), 317(k)(2) of the Public Health Service Act, 42 U.S.C. 247b(k)(2).

1. Background and Purpose

Lupus is the prototypical autoimmune disease, having a wide spectrum of illness that can be limited to the skin or can affect almost any tissue and organ in the body and cause severe morbidity and premature mortality at all ages. While there are several forms of lupus, systemic lupus erythematous (SLE) is the most common and serious form of lupus and has a variety of clinical manifestations. SLE affects from 320,000 to 1.5 million Americans and has strong disparities in incidence and prevalence, affecting women far more than men and minorities more than whites. The causes of SLE are unknown but are believed to be linked to genetic, environmental, and hormonal factors. Much of what is known about SLE comes from convenience samples and tertiary care centers that are not population-based and therefore biased toward the severe end of the disease spectrum. As a result there is a need for a basic epidemiologic understanding of SLE in order to understand the full clinical spectrum and

population burden of the disease. This need is described in the 2015 *National Public Health Agenda for Lupus* (1), and is a priority for the CDC Arthritis Program.

Knowledge of such information on the full spectrum of disease for lupus, which is associated with strong age/sex/race disparities and has had little public health research, can help identify missed opportunities for better treatment, help identify new disease phenotypes based on progression of disease, and help identify factors associated with progression that may play a role in secondary and tertiary prevention.

Component A (Longitudinal Studies in Population-based Cohorts of Adults with Lupus: 3 Year Followup):

Population-based cohorts that include the full spectrum of diagnosed disease provide an opportunity to conduct extended followup studies that address the many unanswered questions that clinicians and researchers have about these relatively uncommon but serious conditions. These questions can only be addressed by examining the same people over the course of the illness. Such lupus followup research studies were funded in 2011 and 2016 in Michigan (University of Michigan) and in 2014 in Georgia (Emory University) and California (University of California - San Francisco) and have provided important followup information for five (Georgia, California) and eight (Michigan) years of followup. The public health need is for additional followup information beyond what has been collected already.

The purpose of Component A is to support research on lupus through a longitudinal followup study designed to follow an established, US-based, population-based cohort of adults age 18 and older with diagnosed lupus (systemic lupus erythematosus {SLE} and skin lupus) that includes followup data collected at least once since 2015**.** The intent of this study is to conduct data collection, building upon the cohort and initial followup activities.

1. The natural history (e.g., severity, morbidity, mortality, disability, co-morbidity, work interference, etc.) of cohort members.
    a. Natural history pertains to the severity of disease (e.g., end-stage renal disease), disease progression (including predictors of progression), morbidity (especially the effects of co-morbid conditions), and mortality.
2. Treatment (e.g., medications, therapy, self-management, etc.) of lupus including the treatment of chronic pain and opioid use.
    a. Lupus is characterized by chronic pain which may be treated with opioid analgesics. Given the current guidelines for prescribing of opioids for chronic pain (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm), data on opioid use among lupus patients will help inform clinical guidelines for the treatment of pain in lupus.
3. Health care access and gaps that adults with lupus experience.
    a. Lupus affects disparate populations (e.g., women, especially African American women; African Americans; Hispanics) who may have problems accessing the necessary health care, particularly specialty care such as for lupus nephritis. Evaluating factors that influence disparities in access to care can help inform interventions to improve care for all lupus patients.
4. Disparities (e.g., age, race/ethnicity, sex) and other factors associated with lupus outcomes.
    a. Data collected with these population-based cohorts will inform potential

culturally-relevant interventions to address disparities.

Such information, if available at all, has generally been available only for hospital-based, specialist-based, or other convenience samples that may not be representative of the full clinical spectrum of lupus. This observational, followup research of established, population-based cohorts will collect data multiple times over 3 years using recurrent surveys, personal contacts, clinical examination, medical records, and genetic and other laboratory testing.

Component B: (A Pediatric Lupus Registry with Longitudinal Followup):

Population-based cohorts of children that include the full spectrum of diagnosed disease provide an opportunity to conduct extended followup studies that address the many unanswered questions that clinicians and researchers have about these relatively uncommon but serious conditions. These questions can only be addressed by examining the same children over the course of the illness, including beyond childhood.

The purpose of this Component B is to support an existing U.S. based registry of children age 0-17 years with diagnosed lupus (SLE and skin lupus). The intent of this study is to gather baseline data for children age 0-17 years and follow up data for this cohort for three additional years. The baseline and follow up data should include these 4 content areas:

1. The natural history (e.g., severity, morbidity, mortality, disability, co-morbidity, school or work interference, etc.) of cohort members.
    a. Natural history pertains to the severity of disease (e.g., end-stage renal disease), disease progression (including predictors of progression), morbidity (especially the effects of co-morbid conditions), and mortality.
2. Treatment (e.g., medications, therapy, self-management, etc.) of lupus including the treatment of chronic pain and opioid use.
    a. Lupus is characterized by chronic pain which may be treated with opioid analgesics. Given the current guidelines for prescribing of opioids for chronic pain (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm), data on opioid use among lupus patients will help inform clinical guidelines for the treatment of pain in lupus.
3. Health care access and gaps that children with lupus experience.
    a. Lupus affects disparate populations (e.g., women, especially African American women; African Americans; Hispanics) who may have problems accessing the necessary health care, particularly specialty care such as for lupus nephritis. Evaluating factors that influence disparities in access to care can help inform interventions to improve care for all lupus patients.
4. Disparities (e.g., age, race/ethnicity, sex) and other factors associated with lupus outcomes.
    a. Data collected with these population-based cohorts will inform potential culturally-relevant interventions to address disparities.

Such information, if available at all, has generally been available only for hospital-based, specialist-based, or other convenience samples that may not be representative of the full clinical spectrum of lupus. This observational, followup research will support a baseline registry (as population-based as possible) and collect data multiple times over the 3-year project period

using recurrent surveys, personal contacts, clinical examination, medical records, and genetic and other laboratory testing.

Healthy People 2020 and other National Strategic Priorities

Lupus is classified as a type of arthritis for public health purposes, so it relates to several national priorities.

This NOFO addresses the Healthy People 2020 focus areas of 1) Arthritis, Osteoporosis, and Chronic Back Conditions; 2) Access to Health Services, 3) Disability and Health; 4) Health Communication and Health Information Technology; 5) Social Determinants of Health and 6) Health-related Quality of Life & Well-being. Analyses from this NOFO may address all nine arthritis objectives on doctor diagnosed arthritis because they address lupus, a condition which is included in the definition of arthritis and other rheumatic conditions. The nine arthritis objectives relate to pain, activity limitations, performing specific joint?related activities, performing personal activities, psychological distress, work, provider counseling, evidence-based education and seeing a health care provider.

This NOFO also implements epidemiology strategies from the *1999 National Arthritis Action Plan ? A Public Health Strategy,* which are a priority for the CDC Arthritis Program. These strategies include: 1) develop population-based, longitudinal data systems to track the occurrence, progress, and impact of arthritis (lupus); 2) identify modifiable risk factors to reduce the incidence of and disability from arthritis (lupus); and 3) study the personal effects of arthritis (lupus). (1)

This NOFO aligns with epidemiology and surveillance strategies and recommendations of the *2015 National Public Health Agenda for Lupus* (2):

Strategy 1-1: Monitor long-term trends in the burden of lupus

Strategy 1-2: Assess and monitor the quality and timeliness of care for people living with lupus

Strategy 1-3: Assess and monitor quality of life among people living with lupus

Strategy 1-5: Expand research in lupus, including epidemiologic, surveillance and public health research

By addressing gender and race disparities in lupus, this NOFO addresses the fourth strategic direction of the National Prevention Strategy (Elimination of Health Disparities). (3)

Also, this NOFO addresses the CDC Strategic Framework Strategy #2: Better prevent the leading causes of illness, injury, disability, and death, by collecting accurate, timely and comprehensive surveillance information on a condition that has been not previously been captured by other population-based data systems. (4)

Public Health Impact

<u>Component A</u> (Longitudinal Studies in Population-based Cohorts of Adults with Lupus: 3 Year Followup):

This research will have a public health impact by identifying strengths and challenges of existing clinical and public health approaches to managing lupus, a clinically complicated

disease, by addressing research questions on natural history, treatment, health care access, and disparities. 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 problems. With this information, clinical and public health approaches can be enhanced to help improve the quality of life of adults with lupus. Also, by examining categories of research interest (e.g., age, sex, race/ethnicity), more culturally relevant interventions can be produced.

Component B (A Pediatric Lupus Registry with Longitudinal Followup):

This research will have a public health impact by identifying strengths and challenges of existing clinical and public health approaches to managing lupus, a particularly clinically complicated disease in children. It will address research questions on natural history, treatment, health care access, and disparities. This research addresses a public health gap for children 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 problems. With this information, clinical and public health approaches can be enhanced to help improve the quality of life of children with lupus. Also, by examining categories of research interest (e.g., age, sex, race/ethnicity), more culturally relevant interventions can be produced.

Relevant Work

CDC has previously funded and is currently funding work on a variety of SLE-relevant activities, including research (i.e., adult lupus registries and followup studies) and non-research (partnerships, raising awareness, etc.), and in *2015 published a National Public Health Agenda for Lupus*, the first-ever such public health agenda (5).

Previous funding (some as early as FY 2003) created five, population-based lupus registries of >400 lupus patients designed to develop credible estimates of the incidence and prevalence of lupus for five race/ethnic groups (Blacks, Whites, Hispanics, Asians, and American Indian/Alaska Natives). These include:

- The Georgia Lupus Registry (Blacks, Whites)
- Michigan Lupus Epidemiology and Surveillance (MILES) Program (Blacks, Whites)
- California Lupus Surveillance Program (Hispanics, Asians)
- Manhattan Lupus Surveillance Program (Hispanics, Asians)
- Indian Health Service Lupus Project (American Indians/Alaska Natives)

From these initial registries, CDC has since funded three studies of established population-based lupus cohorts to determine natural history, treatment, health care access, and disparities over 5+ years. These currently funded projects are being completed by University of Michigan, Emory University, and University of California, San Francisco. These projects have collected data and published findings on the incidence and prevalence of lupus, morbidity (renal disease, health-related quality of life, etc.), health care (diagnosis and management) and disparities (e.g., age, race/ethnicity, sex). (5-11)

The CDC Arthritis Program also funds the Lupus Foundation of America (LFA) and the

American College of Rheumatology (ACR) through a DP15-1511 cooperative agreement to improve the health of individuals with lupus by providing tools to improve overall well-being. Through key stakeholders, awardees are empowering the individual to take action by providing practical resources and skills to achieve increased knowledge of lupus signs and symptoms, to establish lupus patient centered care, and to improve lupus self-management. This work is important to address the limited availability and access to lupus education and resources among these targeted audiences. The ultimate impact can reduce hospitalization rates and improve kidney disease health outcomes.

2. Approach

Intent of this NOFO is to use an existing population based registry and subsequent cohort to collect followup data on 4 important content areas. A population based registry is important because, to date, information has generally only been available for hospital-based, specialist-based, or other convenience samples that may not be representative of the full clinical spectrum of lupus.

Component A (Longitudinal Studies in Population-based Cohorts of Adults with Lupus: 3 Year Followup):

- By the end of the performance period the applicant must collect data on a population based, established cohort of patients with lupus over 3 years.
- Study should involve an existing population-based cohort of >400 adults that includes the full spectrum of disease, SLE and skin lupus, and has been followed for the following content areas for at least 4 years at the time of application.
    - The natural history (e.g., severity, morbidity, mortality, disability, comorbidity, work interference, etc.) of cohort members, and
    - Treatment (e.g., medications, therapy, self-management, etc.) of lupus including the treatment of chronic pain and opioid use, and
    - Health care access and gaps that adults with lupus experience, and
    - Disparities (e.g., age, race/ethnicity, sex) and other factors associated with lupus outcomes.
- Data collection should include the four content areas listed above: natural history, treatment, health care access, and disparities.
- Participate in 1-on-1 bi-monthly conference calls with CDC Project Officer.
- Participate in quarterly conference calls with all sites and CDC Staff.
- Particpate in site visit/reverse site visit with CDC Project Officer as scheduled to discuss project.
- Publish study results (conference abstracts, peer-reviewed manuscripts, etc.).

Component B (A Pediatric Lupus Registry with Longitudinal Followup):

- Study should support a registry of >200 children ages 0-17 years with diagnosed lupus (as population-based as possible) that includes the full spectrum of disease (SLE and skin lupus) with baseline data needed to follow the resulting cohort for the duration of the project period for the following content areas.
    - The natural history (e.g., severity, morbidity, mortality, disability, comorbidity,

school or work interference, etc.) of cohort members, and
    - Treatment (e.g., medications, therapy, self-management, etc.) of lupus including the treatment of chronic pain and opioid use, and
    - Health care access and gaps that children with lupus experience, and
    - Disparities (e.g., age, race/ethnicity, sex) and other factors associated with lupus outcomes.
- By the end of the performance period the applicant must establish baseline data collection, collect at least 1 year of followup data and publish results.
- Data collection during the period of performance (baseline and followup) should include the four content areas listed above: natural history, treatment, health care access, and disparities.
- Participate in 1-on-1 bi-monthly conference calls with CDC Project Officer.
- Participate in quarterly conference calls with Component A sites and CDC Staff.
- Participate in site visit/reverse site visit with CDC Project Officer as scheduled to discuss project.
- Publish study results (conference abstracts, peer-reviewed manuscripts, etc.).(12-17)

Applicants can apply for Component A, Component B or both but there must be separate applications if applying for both.

Objectives/Outcomes

Component A (Longitudinal Studies in Population-based Cohorts of Adults with Lupus: 3 Year Followup):
Objective 1: Determine longer term natural history (e.g., severity, morbidity, mortality, disability, comorbidity, work interference, etc.) of adults with lupus.
Outcomes: Collect, analyze and publish data on the long-term (8+ years of followup) natural history of lupus among a population-based cohort of adult lupus patients.

Objective 2: Document the treatment (e.g., type, appropriateness, medications, physical therapies, mental health, self-management, etc.) of adults with lupus including chronic pain and opioid use.
Outcomes: Presentations (e.g., conferences) and publications providing descriptive analyses of type and extent of clinical treatment (e.g., blood testing, physical examination, pharmacologics, non-pharmacologic interventions) among a population-based cohort of lupus patients and identifying disparities in treatment by age, sex, race/ethnicity.

Objective 3: Determine the health care access (e.g., ambulatory care, hospitalizations, emergency room visits, insurance status, access to specialists such as rheumatologists, nephrologists, etc.) and gaps that adults 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).
Outcomes: Presentations (e.g., conferences) and publications providing descriptive analyses of health care access and gaps in health care access that adults with lupus experience.

Objective 4: Assess disparities and other factors associated with lupus outcomes by categories of interest (e.g., age, sex, and race/ethnicity group).
Outcomes: Presentations and publications on lupus outcomes by age, sex, and race/ethnicity.

Objective 5: Presentations (e.g., conferences) and publications of study results to various audiences (health professionals, public health practitioners, persons with lupus, etc.) including publication in peer reviewed journals, presentations at conferences and disseminate findings using health communications though partnerships with patient disease associations (e.g., Lupus Foundation of America).

Component B (A Pediatric Lupus Registry with Longitudinal Followup):
Objective 1: Determine the natural history (e.g., severity, morbidity, mortality, disability, comorbidity, school or work interference, etc.) of children with lupus.
Outcomes: Collect, analyze and publish data on the baseline registry and followup cohort for natural history of lupus among children.

Objective 2: Document the treatment (e.g., type, appropriateness, medications, physical therapies, mental health, self-management, etc.) of children with lupus including chronic pain and opioid use.
Outcomes: Presentations (e.g., conferences) and publications providing descriptive analyses of type and extent of clinical treatment (e.g., blood testing, physical examination, pharmacologics, non-pharmacologic interventions) among a population-based cohort of lupus patients and identify disparities in treatment by age, sex, race/ethnicity.

Objective 3: Determine the health care access (e.g., ambulatory care, hospitalizations, emergency room visits, insurance status, access to specialists such as rheumatologists, nephrologists, etc.) and gaps that children 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).
Outcomes: Presentations (e.g., conferences) and publications providing descriptive analyses of health care access and gaps in health care access that adults with lupus experience.

Objective 4: Assess disparities and other factors associated with lupus outcomes by categories of interest (e.g., age, sex, and race/ethnicity group).
Outcomes: Presentations and publications on lupus outcomes by age, sex, and race/ethnicity.

Objective 5: Presentations (e.g., conferences) and publications of study results to various audiences (health professionals, public health practitioners, persons with lupus, etc.) including publication in peer reviewed journals, presentations at conferences and disseminate findings using health communications though partnerships with patient disease associations (e.g., Lupus Foundation of America).

Target Population

Component A (Longitudinal Studies in Population-based Cohorts of Adults with Lupus: 3 Year Followup):
The target population is adults aged 18 and older with SLE and/or skin lupus who were identified through a U.S, population-based registry and have 4 years of followup at time of application for the four content areas listed above under Approach.

Component B (A Pediatric Lupus Registry with Longitudinal Followup):
The target population is children age 0-17 years with diagnosed lupus (SLE and/or skin lupus) for a registry as geographically population-based as possible.

Collaboration/Partnerships

Components A and B:
Collaboration or partnerships may be needed to guarantee access to the required data (both existing and followup data), and to those with the requisite expertise in lupus (e.g., international lupus experts), data management, and longitudinal data analysis needed to achieve the objectives of this NOFO. For example, the applicant may partner with the state Health Department and the vital statistics system to match mortality data to the the lupus cohort. The applicant will work with CDC collaborators and other grantees to design, implement, and analyze data across sites as needed.

Evaluation/Performance Measurement

Components A and B:
Awardees will be expected to provide a timeline of key milestones (matched cohort with vital statistics, followup of cardiovascular events, etc.), plans for data assurance, confidentiality and quality, and plans for conference calls/site visits and drafting related minutes and reports.

Translation Plan

Component A (Longitudinal Studies in Population-based Cohorts of Adults with Lupus: 3 Year Followup):

Awardees will be expected to provide a plan to submit and present abstracts at relevant professional meetings (e.g., the American College of Rheumatology, biannual Armonk (NY) Lupus Meeting) and to publish full-length manuscripts in peer reviewed journals. It is expected that 3-5 manuscripts per year will be submitted to peer reviewed journals by each awardee. Priority findings to be disseminated should include natural history, treatment, health care access and disparities in these outcomes.

Component B (A Pediatric Lupus Registry with Longitudinal Followup):

Awardees will be expected to provide a plan to submit and present abstracts at relevant professional meetings (e.g., the American College of Rheumatology, biannual Armonk (NY) Lupus Meeting, pediatric meetings) and to publish full-length manuscripts in peer reviewed journals. It is expected that at least an average of 2 manuscripts per year will be submitted to peer reviewed journals by the awardee during the project period. Priority findings to be disseminated should include natural history, treatment, health care access and disparities in these outcomes.

OMB/PRA is expected to apply.

References:

1. Healthy People 2020 available at https://www.healthypeople.gov/2020/topics-objectives/topic/Arthritis-Osteoporosis-and-Chronic-Back-Conditions/objectives
2. The National Prevention Strategy can be found at: http://www.surgeongeneral.gov/priorities/prevention/strategy/report.pdf.
3. CDC Strategic Framework Strategy #2 can be found at https://www.cdc.gov/about/organization/strategic-framework/index.html#B2

4. 2015 National Public Health Agenda for Lupus is available at https://www.lupus.org/general-

news/entry/national-lupus-public-health-agenda-provides-roadmap.
5. 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.
6. 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.
7. 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
8. Lim S, Drenkard C, McCune WJ, et al. Population-based lupus registries: Advancing our epidemiologic understanding. Arthritis Rheum. 2009;61(10):1462?1466.
9. Plantinga L, Lim SS, Patzer R, et al. Incidence of end-stage renal disease among newly diagnosed systemic lupus erythematosus patients: The Georgia Lupus Registry. Arthritis Care Res (Hoboken). 2015;68:357-365.
10. Plantinga L, Lim SS, Bowling CB, Drenkard C. Association of age with health-related quality of life in a cohort of patients with systemic lupus erythematosus: the Georgians Organized Against Lupus study. Lupus Sci Med. 2016:3e000161.
11. McDougall JA, Helmick CG, Lim SS, et al. Differences in the diagnosis and management of systemic lupus erythematosus by primary care and specialist providers in the American Indian/Alaska Native population. Lupus. [published online March 19, 2018]. doi: 10.1177/0961203318763529
12. Demirkaya E, Concolaro A, Sonmez HE, Giancane G, Simsek D, Ravelli A. Current Research in Outcomes Measures for Pediatric Rheumatic and Autoimflammatory Diseases. Curr Rheumatol Repo 2016;18(8):DOI 10.1007/s11926-015-0558-4.13.Hersh AO, Case SM, Son MB. Predictors of Disability in a Childhood-onset Systemic Lupus Erythematosus Cohort: Results from the CARRA Legacy Registry. Lupus 2018;27:494-500.
Borgia RE, Silverman ED. Childhood-onset Systemic Lupus Erythematosus: An Update. Curr Opin Rheumatol. 2015;27(5):483-92. doi: 10.1097/BOR.0000000000000208.

13. Aggarwal A, Srivastava P. Childhood Onset Systemic Lupus Erythematosus: How is it different from adult SLE? International Journal of Rheumatic Diseases 2015;18:182-191.
14. Thakral A, Klein-Gitelman MS. An Update on Treatment and Management of Pediatric Systemic Lupus Erythematosus. Rheumatol Ther. 2016 Dec;3(2):209-219. Epub 2016 Sep 30.

15. Beukelman T, Kimura Y, Ilowite NT, Mieszkalski K, Natter MD, Burrell G, Best B, Jones J, Schanberg LE. The new Childhood Arthritis and Rheumatology Research Alliance (CARRA) registry: design, rationale, and characteristics of patients enrolled in the first 12 months. Pediatric Rheumatology201715:30 https://doi.org/10.1186/s12969-017-0160-6
16. Luca NJC, Feldman BM. Health Outcomes of Pediatric Rheumatic Diseases. Best Practice & Research Clinical Rheumatology 2014;28:331-350.

Section II. Award Information

Funding Instrument Type:	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: $10,500,000

Component A: 9/1/19 – 8/31/20, is $2,700,000 for 3 awards. The average award amount is $900,000 per award in year one.The estimated total funding (direct and indirect) for the entire period of performance, 9/1/19 – 8/31/22, is $8,100,000 for 3 awards.

Component B: 9/1/19 – 8/31/20, is $800,000 for 1 award. The estimated total funding (direct and indirect) for the entire period of performance, 9/1/19 – 8/31/22, is $2,400,000.

Anticipated Number of Awards: 4

Component A: 3 awards

Component B: 1 award

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

Award Ceiling: $1,000,000 Per Budget Period
Award Floor: $700,000 Per Budget Period
Total Period of Performance Length: 3 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 (http://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.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
State governments
County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions

of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
For profit organizations other than small businesses
Small businesses
Others (see text field entitled "Additional Information on Eligibility" for clarification)
Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility"

Additional Eligibility Category:

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 include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

Eligibility applicants must meet the following criteria:

Component A: (Longitudinal Studies of Lupus in Population-based cohorts of Adults with Lupus: 3 Year Followup):

Criteria 1. Applicant must have an existing U.S. population-based cohort with > 400 adults ages 18 and greater at baseline, with SLE and/or skin lupus.

Criteria 2. Applicant must have at least 4 years of followup at time of application for the four content areas listed in the Approach section above (natural history, treatment, health care

access, and disparities).

Component B: (A Pediatric Lupus Registry with Longitudinal Followup):

Criteria 1. Applicant must have access to an existing cohort with 200+ diagnosed U.S. lupus patients ages 0-17 years at baseline in an area that is geographically population-based.

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.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Evidence for the special eligibility criteria listed in number 3 above documentation must be presented in Appendix A of the application. If your application is incomplete or non-responsive to these requirements, it will not enter into the review process.

Component A (Longitudinal Studies in Population-based Cohorts of Adults with Lupus: 3 Year Followup):

Criteria 1: Existing population-based cohort with > 400 adults ages 18 and greater at baseline, with SLE and/or skin lupus.

- Provide a letter stating they have access to a cohort with the stated requirements.

Criteria 2: Applicant must have at least 4 years of followup at time of application for the four content areas:

1. Natural history (e.g., severity, morbidity, mortality, disability, comorbidity, work interference, etc.) of cohort members,
2. Treatment (e.g., medications, therapy, self-management, etc.) of lupus including the treatment of chronic pain and opioid use,
3. Health care access and gaps that adults with lupus experience, and
4. Disparities (e.g., age, race/ethnicity, sex) associated with lupus outcomes.

- Provide one or more figures, tables, diagrams or publications demonstrating data collection related to the four content areas over at least a 4 year period.

Component B: (A Pediatric Lupus Registry with Longitudinal Followup):

Criteria 1. Existing population-based cohort of at least 200+ diagnosed U.S. lupus patients ages 0-17 years at baseline in areas that are geographically population-based.

- Provide a letter stating they have access to a cohort with the stated 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.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https:// eportal.nspa.nato. int/ AC135Public/ Docs/ US%20Instructions%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/.
- 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 Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principle 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 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. 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 https://www.sam.gov/index.html.
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 FOA 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.

Only one application per institution (normally identified by having a unique DUNS number) per component is allowed. Separate applications are required if applying for more than one component.

Section IV. Application and Submission Information

1. Address to Request Application Package

In order to use ASSIST, applicants must visit https://public.era.nih.gov/assist 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:

- E-mail: http://grants.nih.gov/support/index.html
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552. The NIH eRA Service desk

is available Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf, 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.

3. Letter of Intent

Due Date for Letter of Intent: **02/08/2019**

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CDC staff to estimate the potential review workload and plan the review.

By February 8, 2019, prospective applicants are asked to submit a letter of intent that includes the following information:

- Name of the Applicant
- Descriptive title of proposed research
- 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 of intent should be sent to:

Jessie Hood, ScD, MPH
Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30342

Telephone: 404-639-1415
Email: JVR4@cdc.gov

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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf and https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf 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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf 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:
• Descriptions of the data to be produced in the proposed project
• How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
• 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
• Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified
Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

Research Plan
Applicants can apply for Component A, Component B or both but there must be separate applications if applying for both.

For each Component, the applicant's research plan should address activities that will be conducted over the entire 3-year period of performance and should include the items listed below. NOTE: The Research Strategy is divided into three parts: (1) Significance (2) Innovation and (3) Approach.

A population based registry is important because, to date, information has generally only been available for hospital-based, specialist-based, or other convenience samples that may not be representative of the full clinical spectrum of lupus.

Component A (Longitudinal Studies of Lupus in Population-based Cohorts of Adults with Lupus: 3 Year Followup):

- Define (geographic region) and describe the existing cohort, in terms of natural history, treatment, access to care, and disparities:

1. The natural history (e.g., severity, morbidity, mortality, disability, co-morbidity, school or work interference, etc.) of cohort members.
    a. Natural history pertains to the severity of disease (e.g., end-stage renal disease), disease progression (including predictors of progression), morbidity (especially the effects of co-morbid conditions), and mortality.
2. Treatment (e.g., medications, therapy, self-management, etc.) of lupus including the treatment of chronic pain and opioid use.

   a. Lupus is characterized by chronic pain which may be treated with opioid analgesics. Given the current guidelines for prescribing of opioids for chronic pain (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm), data on opioid use among lupus patients will help inform clinical guidelines for the treatment of pain in lupus.
3. Health care access and gaps that adults with lupus experience.
   a. Lupus affects disparate populations (e.g., women, especially African American women; African Americans; Hispanics) who may have problems accessing the necessary health care, particularly specialty care such as for lupus nephritis. Evaluating factors that influence disparities in access to care can help inform interventions to improve care for all lupus patients.
4. Disparities (e.g., age, race/ethnicity, sex) and other factors associated with lupus outcomes.
   a. Data collected with these population-based cohorts will inform potential culturally-relevant interventions to address disparities.

- Demonstrate the ability to follow the established cohort for the 3 year of the period of performance.
- Provide overall aims or objectives for the study.
- Provide a map of the geographic area of the original population-based registry.
- Case finding statement from the original registry's final protocol that demonstrates it was intended to be population-based, and list of any later departures from that protocol.
- Provide a table with demographics (age, sex, race/ethnicity) of the existing population-based cohort of >400 adults age 18 and greater at baseline and followup. Provide list of lupus diagnoses for the cohort members.
- Describe process for developing the protocol, methods, and quality assurance to be used for this study
- Describe the plan for maintaining appropriate Institutional Review Board approvals for all institutions or individuals participating in research involving human subjects.
- Describe how the study will be implemented, including plans for acquiring the needed data, the number and type of project staff that would be involved, and potential barriers (e.g., IRB, patient consent, resistance/inability of primary care and other providers to share needed data, loss-to-followup) to be addressed.
- Describe information technology (equipment, software, expertise) to be used.
- Provide a staffing plan with roles and responsibilities for each staff member.
- Identify the data to be collected and the related hypotheses relevant to the data.
- Discuss the logistics of and barriers to gathering relevant data from patients and the health care system, including patient recruitment and consent, access to medical records, and maintaining contact.
- Provide expected outcomes by the end of the project period.
- Describe plans for data analyses to be undertaken including, where possible, the responsible analyst.
- Describe how the results of the research will offer improvements in public health programs, practice, or systems.
- Describe how the applicant will work with CDC collaborators and other grantees to

design, implement, and analyze data across sites as needed.
- Provide a dissemination plan to present at scientific conferences and rapidly publish findings in peer-reviewed literature.

Component B (A Pediatric Lupus Registry with Longitudinal Followup):

- Define (geographic region) and describe the existing cohort, in terms of natural history, treatment, access to care, and disparities:

1. The natural history (e.g., severity, morbidity, mortality, disability, co-morbidity, school or work interference, etc.) of cohort members.
    a. Natural history pertains to the severity of disease (e.g., end-stage renal disease), disease progression (including predictors of progression), morbidity (especially the effects of co-morbid conditions), and mortality.
2. Treatment (e.g., medications, therapy, self-management, etc.) of lupus including the treatment of chronic pain and opioid use.
    a. Lupus is characterized by chronic pain which may be treated with opioid analgesics. Given the current guidelines for prescribing of opioids for chronic pain (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm), data on opioid use among lupus patients will help inform clinical guidelines for the treatment of pain in lupus.
3. Health care access and gaps that adults with lupus experience.
    a. Lupus affects disparate populations (e.g., women, especially African American women; African Americans; Hispanics) who may have problems accessing the necessary health care, particularly specialty care such as for lupus nephritis. Evaluating factors that influence disparities in access to care can help inform interventions to improve care for all lupus patients.
4. Disparities (e.g., age, race/ethnicity, sex) and other factors associated with lupus outcomes.
    a. Data collected with these population-based cohorts will inform potential culturally-relevant interventions to address disparities.

- Demonstrate the ability to support an existing registry and follow the established cohort for the project period.
- Provide a map of the proposed geographic area for the registry (as population-based as possible).
- Proposed case finding methods designed to find diagnosed cases of lupus among children.
- Provide overall aims or objectives for the study.
- Describe process for developing the protocol, methods, and quality assurance to be used for this study, including case finding methods.
- Describe the plan for maintaining appropriate Institutional Review Board approvals for all institutions or individuals participating in research involving human subjects.
- Describe how the study will be implemented, including plans for acquiring the needed data, the number and type of project staff that would be involved, and potential barriers (e.g., IRB, patient/parental consent, resistance/inability of primary care and other

providers to share needed data, loss-to-followup) to be addressed.

- Describe information technology (equipment, software, expertise) to be used.
- Provide a staffing plan with roles and responsibilities for each staff member.
- Identify the data to be collected and the related hypotheses relevant to the data.
- Discuss the logistics of and barriers to gathering relevant data from patients and the health care system, including patient recruitment and consent, access to medical records, and maintaining contact, especially as this may apply to a geographically wide-spread area.
- Provide expected outcomes by the end of the project period.
- Describe plans for data analyses to be undertaken including, where possible, the responsible analyst.
- Describe how the results of the research will offer improvements in public health programs, practice, or systems.
- Describe how the applicant will work with CDC collaborators and other grantees to design, implement, and analyze data across sites as needed.
- Provide a dissemination plan to present at scientific conferences and rapidly publish findings in peer-reviewed literature.

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 publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

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 35 pages for all appendices.

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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf.

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.
Organizations must submit applications using the ASSIST web-based application preparation and submission process.
ASSIST will validate applications before submission. If the system detects errors, then the applicant must correct errors before their application can be submitted.
Applicants are responsible for viewing their application 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 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)
If the applicant encounters problems that prevent the ability to submit an application which cannot be resolved by Grants.gov or NIH eRA Service Desks, then applicants must contact CDC Technical Information Management Section (TIMS) at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date. Therefore, 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**", 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 and ogstims@cdc.gov 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: **03/08/2019**

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

10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (http:// www. whitehouse.gov/ omb/ grants_spoc).

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 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.
In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).
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.
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. 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/additionalrequirements/ar-25.html for revised AR-25.

All HHS/CDC awards are subject to the federal regulations, 45 CFR 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.

Also, I recommend including why there are specific publication and presentation requirements in terms of the number.

In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).

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.

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.

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/additionalrequi

rements/ar-25.html for revised AR-25.

Applicants are advised that any activities involving information collection (i.e., surveys, questionnaires, etc.) from 10 or more non-Federal individuals/entities are subject to OMB/PRA requirements and may require the CDC to coordinate an OMB Information Collection Clearance was not provided in the NOFO.

12. 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."

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 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.
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.
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.

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?

Does the work address a scientific problem of great importance to public health research and/or practice? What is the potential or actual impact of the research on public health, epidemiology and clinical treatment?

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?

Do the investigators have a successful track record conducting registry-based longitudinal followup studies of lupus?

Have previous research results provided high quality outputs and contributed to improvements in public health practice and population health?

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?

Is the proposed research innovative in registry-based followup study methodology and yet offer reasonable potential for concrete applications of interest and value to CDC?

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?

Does the applicant demonstrate sufficient staff, resources and study design to accomplish the following:

Component A:

- By the end of the performance period the applicant must collect data on a population based, established cohort of patients with lupus over 3 years.
- Study should involve an existing population-based cohort of >400 adults that includes the full spectrum of disease, SLE and skin lupus, and has been followed for the following content areas for at least 4 years at the time of application.
    - The natural history (e.g., severity, morbidity, mortality, disability, comorbidity, work interference, etc.) of cohort members, and
    - Treatment (e.g., medications, therapy, self-management, etc.) of lupus including the treatment of chronic pain and opioid use, and
    - Health care access and gaps that adults with lupus experience, and
    - Disparities (e.g., age, race/ethnicity, sex) and other factors associated with lupus outcomes.
- Data collection should include the four content areas listed above: natural history, treatment, health care access, and disparities.

- Participate in 1-on-1 bi-monthly conference calls with CDC Project Officer.
- Participate in quarterly conference calls with all sites and CDC Staff.
- Participate in site visit/reverse site visit with CDC Project Officer as scheduled to discuss project.
- Publish study results (conference abstracts, peer-reviewed manuscripts, etc.).

Component B:

- Study should support a registry of >200 children ages 0-17 years with diagnosed lupus (as population-based as possible) that includes the full spectrum of disease (SLE and skin lupus) with baseline data with the ability to follow this cohort for the duration of the project period for the following content areas.
    - The natural history (e.g., severity, morbidity, mortality, disability, comorbidity, school or work interference, etc.) of cohort members, and
    - Treatment (e.g., medications, therapy, self-management, etc.) of lupus including the treatment of chronic pain and opioid use, and
    - Health care access and gaps that children with lupus experience, and
    - Disparities (e.g., age, race/ethnicity, sex) and other factors associated with lupus outcomes.
- By the end of the performance period the applicant must establish baseline data collection, collect at least 1 year of followup data and publish results.
- Data collection during the period of performance (baseline and followup) should include the four content areas listed above: natural history, treatment, health care access, and disparities.
- Participate in 1-on-1 bi-monthly conference calls with CDC Project Officer.
- Participate in quarterly conference calls with Component A sites and CDC Staff.
- Participate in site visit/reverse site visit with CDC Project Officer as scheduled to discuss project.
- Publish study results (conference abstracts, peer-reviewed manuscripts, etc.).(12-17)

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.

Does the application describe how the results from the research will be disseminated and ultimately used?

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?

Does the 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 five 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) adequacy of veterinary care; 4) 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 5) 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/VASchecklist.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.

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:

• Type of data to be produced in the proposed project;
• Mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights);
• 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.

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.

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

decisions:

- 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 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 subpart F 45 CFR 75 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).

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:

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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 apply 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 the 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 following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 75 and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officer are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as

defined below.

Components A & B

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
- Oversight of all management, administrative, data security, and scientific aspects of the project.
- Maintain an effective and adequate management and staffing plan.
- Continue to build and maintain partnerships with stakeholders.
- Serve on Coordinating Committee and other workgroups as requested; participate in monthly conference calls, and participate in annual site visits as scheduled.
- Assign staff to attend conference calls and PI meetings as relevant to their duties.
- Obtain/maintain approvals of protocol(s) through designated Institutional Review Board (IRB), assure the protocol(s) (is/are) conducted in compliance with the terms and conditions of the IRB, and amend protocol(s) as needed. Provide approval letters to CDC.
- Assure and maintain the confidentiality of all registry and cohort study data.
- Foster and maintain regular communication with the other grantees and CDC project staff.
- OMB/PRA requirements may apply to the research studies. If OMB applies, collaborate with CDC-led effort to develop OMB submission package.
- Analyze data and publish data on high priority topics:
    - Component A: Analyze data and publish at least 3 manuscripts on high priority topics per year.
    - Component B: Analyze data and publish an average of 2 manuscripts on high priority topics per year.
- Present results at professional society, patient advocacy groups or stakeholder conferences:
    - Component A: Present results at least 3 professional society, patient advocacy group, or stakeholder conferences.
    - Component B: Present results at an average of at least 1 professional society, patient advocacy group, or stakeholder conferences per year.
- Maintain and adequate staffing plan to ensure publication and presentations requirements are met.
- Serve on Lupus Workgroup meetings, and other workgroups as requested; participate in monthly conference calls

Awardees 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.

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- 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

In this cooperative agreement, a NCCDPHP Project Officer (PO) is a partner with scientific and programmatic involvement during the conduct of the project through technical assistance, advice, and coordination. The PO will:

- Assist grantees with building partnerships with stakeholders.
- Provide expertise and guidance on the content, implementation, and, if needed, revision of the project-developed protocols.
- Hold monthly calls and periodic site visits as needed with grantees to determine the adequacy of the research and to monitor performance against approved project objectives.
- Support the grantees activities in data management, analysis and dissemination.
- Provide technical assistance to resolve problems in case ascertainment and data collection procedures.
- Assist in the analyses, interpretation, and reporting of findings in the literature.
- Obtain and maintain IRB approvals as required by CDC when CDC is engaged in research involving human subjects.
- Organize and lead annual in-person Principal Investigator meetings hosted either at CDC facilities in Atlanta or at an awardee site location.
- Coordinate and facilitate discussion on conference calls; develop agendas and provide meeting minutes; followup with sites on action items from calls. Facilitate communication among committees and sites.
- Provide technical assistance for health communications, including plain language resources and CDC's Clear Communications Index.
- Provide day-to-day programmatic, administrative, and fiscal management in support of the project as defined above.

Additionally, an HHS/CDC Project Officer or other HHS/CDC staff will provide day-to-day programmatic, administrative, and fiscal management in support of the project as defined above. HHS/CDC will have primary responsibility for obtaining OMB-PRA approval for the project information collections.

Additionally, an HHS/CDC agency Program Official will be responsible for the normal scientific and programmatic stewardship of the award. 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.

All responsibilities are divided between awardees and CDC staff as described above.

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 contributed 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:

https://era.nih.gov/docs/Commons_UserGuide.pdf

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 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. 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 will continue to be 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 concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://grants.nih.gov/support/index.html

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https:// commons. era.nih.gov/ commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

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.

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

CDC Technical Information Management Section (TIMS)
Telephone 770-488-2700
Email: ogstims@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time

Scientific/Research Contact(s)

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Financial/Grants Management Contact(s)

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Email: HFO8@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 Federal Regulations.

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations. Section 301(a) of the Public Health Service, 42 U.S.C. 241(a), 317(k)(2) of the Public Health Service Act, 42 U.S.C. 247b(k)(2) and use Assistance Listing (formally known as CFDA) 93.283.