

Centers for Disease Control and Prevention

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

Reducing Inequities in Cancer Outcomes through Community-Based Interventions on Social Determinants of Health

RFA-DP-21-003

Application Due Date: 02/10/2021

Reducing Inequities in Cancer Outcomes through Community-Based Interventions on Social Determinants of Health

RFA-DP-21-003

TABLE OF CONTENTS

Part 1. Overview Information
- Key Dates
- Required Application Instructions
- Executive Summary

Part 2. Full Text
- Section I. Funding Opportunity Description
- Section II. Award Information
- Section III. Eligibility Information
- Section IV. Application and Submission Information
- Section V. Application Review Information
- Section VI. Award Administration Information
- Section VII. Agency Contacts
- Section VIII. Other Information

Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

National Center for Chronic Disease Prevention and Health Promotion

Notice of Funding Opportunity (NOFO) Title

Reducing Inequities in Cancer Outcomes through Community-Based Interventions on Social Determinants of Health

Activity Code

U01

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-21-003

Assistance Listings (CFDA) Number(s)

93.068

Category of Funding Activity:

Health

NOFO Purpose

The purpose of this NOFO is to conduct evaluation research to build an evidence base of innovative, community-based interventions across multiple social determinants of health to reduce racial and ethnic disparities related to cancer outcomes. The purpose will be achieved through three (3) components.

Component A: Primary Cancer Prevention – evaluation of the implementation, impact, and causal mechanisms of an intervention's effect to reduce racial or ethnic inequities in cancer risk at the population level.

Component B: Cancer Screening – evaluation of the implementation, impact, and causal mechanisms of an intervention's effect to reduce racial or ethnic inequities in the receipt of appropriate screening services for breast, cervical, colorectal or lung cancer.

Component C: Health and Wellbeing of Cancer Survivors – evaluation of the implementation, impact, and causal mechanisms of an intervention's effect to reduce racial or ethnic inequities in the health and wellbeing of cancer survivors.

Key Dates

Publication Date:

To receive notification of any changes to RFA-DP-21-003, 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:	**01/11/2021**
Application Due Date:	**02/10/2021**

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:	**04/09/2021**
Secondary Review:	**05/12/2021**
Estimated Start Date:	**09/30/2021**
Expiration Date:	**02/11/2021**
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.

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

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

Apply Electronically

Executive Summary

- **Purpose.** The purpose of this NOFO is to conduct evaluation research to build an evidence base of innovative, community-based interventions across multiple social determinants of health to reduce racial and ethnic disparities related to cancer outcomes. For this NOFO, evaluation research is defined as the systematic application of public health research procedures for assessing the conceptualization, design, implementation, effectiveness and utility of public health interventions. Cancer prevention is defined as reduced population risk for cancer. The purpose will be achieved through three (3) components.

  Component A: Primary Cancer Prevention – evaluation of the implementation, impact, and causal mechanisms of an intervention's effect to reduce racial or ethnic inequities in cancer risk at the population level.

  Component B: Cancer Screening – evaluation of the implementation, impact, and causal mechanisms of an intervention's effect to reduce racial or ethnic inequities in the receipt of appropriate screening services for breast, cervical, colorectal or lung cancer.

  Component C: Health and Wellbeing of Cancer Survivors – evaluation of the implementation, impact, and causal mechanisms of an intervention's effect to reduce racial or ethnic inequities in the health and wellbeing of cancer survivors.

- **Mechanism of Support.** Cooperative Agreement
- **Funds Available and Anticipated Number of Awards.** The estimated total funding (direct and indirect) for the five-year period of performance, September 30, 2021 to September 29, 2026, is $15,000,000 to fund three (3) awards, one in each of the three Components.
- **Budget and Period of Performance.** The estimated total funding for the first budget period, 9/30/2021-9/29/2022, is $3,000,000 (direct and indirect). The estimated total funding for the entire period of performance, 9/30/2021-9/29/2026, is $15,000,000 (direct and indirect).

  Component A: Primary Cancer Prevention
  Period of Performance: 5 years (09/30/2021 to 09/29/2026)

Estimated Funding Per Year: Up to $1,000,000

Component B: Cancer Screening
Period of Performance: 5 years (09/30/2021 to 09/29/2026)
Estimated Funding Per Year: Up to $1,000,000

Component C: Health and Wellbeing of Cancer Survivors
Period of Performance: 5 years (09/30/2021 to 09/29/2026)
Estimated Funding Per Year: Up to $1,000,000

- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic minority groups as well as individuals with disabilities are always encouraged to apply through their organization.
- **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.
- **Number of Applications.** Only one application per institution (normally identified by having a unique DUNS number) is allowed. Applicants may apply for one (1) Component of funding (Component A, or Component B, or Component C).
- **Application Type.** New
- **Special Date(s).** None
- **Application Materials.** See Section IV.1 for application materials. Please note that Form F is to be used when downloading the application package that is available at https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/research-forms-f.pdf

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

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

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

1. Background and Purpose

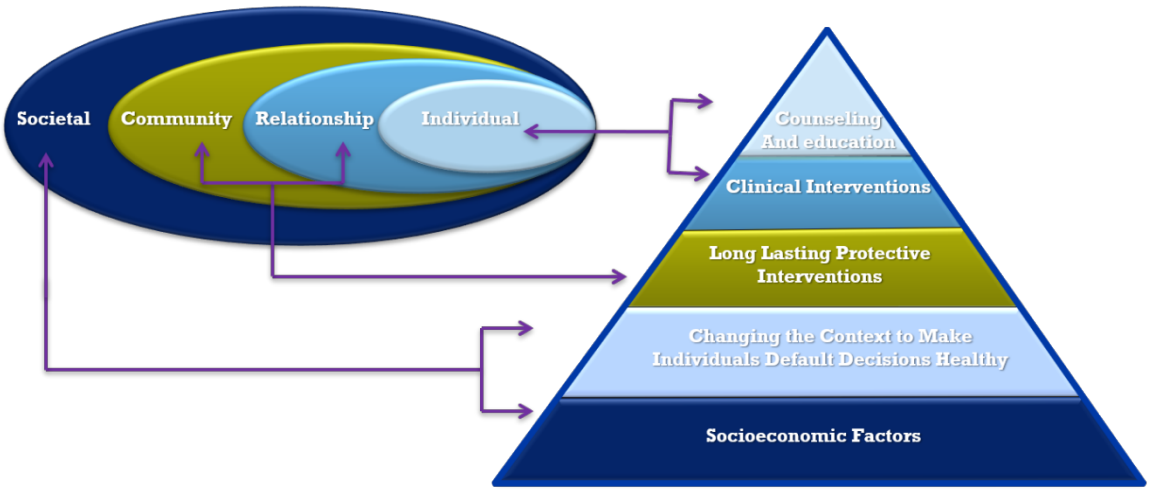
It has been said that a person's zip code is more important than their genetic code for health.[1]

This statement reflects the large body of scientific evidence linking nonmedical factors, such as economic opportunities and systemic racism, with health.[2-7] Today, the COVID-19 pandemic has increased national attention on the many societal-level inequities that impact racial and ethnic minority groups and can shape opportunities over a lifetime.[2, 8] These factors, commonly referred to as social determinants of health, also explain long-standing disparities in cancer outcomes across different racial and ethnic groups.[9]

Cancer-related health outcomes often follow similar geographical gradients as social determinants of health.[10] Residential segregation based on race has had consequences for race-based disparities in cancer and other health outcomes.[11, 12] Neighborhoods provide a set of social and environmental circumstances and resources that can be either healthful or harmful. A review of 17 studies on residential segregation [13] found most studies reported racial segregation contributed to cancer disparities, including later stage at diagnosis, higher mortality rates, and lower survival rates, even after adjustment for socioeconomic status. In addition, under-resourced and racially segregated communities are more likely to have higher levels of environmental pollution,[14, 15] which could negatively impact cancer outcomes. Racial residential segregation is regarded as one of the fundamental causes of racial disparities in health.[16]

To reduce disparities and improve population health, the socio-ecological framework highlights the interrelationships between aspects of the social and physical environments that operate at multiple levels to influence health.[17] Consistent with this framework, change can occur at individual, interpersonal, community, and structural levels to promote cancer prevention and significantly reduce health disparities. The structural social determinants, the focus of this NOFO, correspond to the bottom tiers of the Health Impact Pyramid, where action taken can have the greatest population impact [18, 19], see figure. Structural social determinants influence opportunities, resources, and living conditions at the individual level.[9, 20] Scholars have noted that race disparities affect all aspects of the social and physical environments through a system of race discrimination, and disparities in one aspect reinforce disparities in another.[12, 21]

Frieden Health Impact Pyramid and Socioecological Framework



Adapted from: Frieden, T. (2010). A Framework for Public Health Action: The Health Impact Pyramid. American Journal of Public Health.100:590–595.

Several authors have pointed to the inability of traditional studies of health disparities and program evaluation to inform and affect structural and policy change.[2, 9, 22-24] In 2008, the Commission on Social Determinants of Health of the World Health Organization issued a report with findings and recommendations for closing the gap in health equity within a generation.[4] The commission emphasized the need to improve the conditions of daily life and tackle inequities in the distribution of power, money, and resources. Among the many factors discussed by this commission, working conditions and the nature of work were identified as important to health. Work provides financial security and often health insurance, and paid leave, when available, can increase the uptake of cancer screening.[25] This report also emphasized the need for evidence on the effectiveness of action on social determinants to reduce health inequities.

A recent review article examined the implementation of interventions to address social determinants of health within the healthcare sector involving mostly people with low-incomes from specific racial or ethnic minority groups and cancer screening.[26] Many of the interventions addressed immediate social needs, such as transportation and childcare assistance to attend screening appointments and patient navigators, rather than the structural factors underlying those needs. In contrast, other authors have described efforts to engage community residents and leaders as equal partners in structural and systemic interventions, not just as the recipients of social services.[27, 28] An equity-based approach would involve those most impacted and aim for sustained community change and transformative change in power, equity, and justice.[28] In 2020, the American Society of Clinical Oncology (ASCO) issued a policy statement on cancer disparities and health equity.[29] Among its recommendations, ASCO called upon professional organizations to pursue community partnerships, multisector

collaborations, and local capacity building to address societal conditions (structural barriers) that preserve and promote inequities.

Various interventions including policy change are being implemented in communities across the country to address social determinants of health, but their impact on health has rarely been evaluated or quantified.[30-32] The Community Preventive Services Task Force has reviewed evidence on intervention approaches for health equity.[33] However, the available evidence is limited on the impact of interventions to address social determinants of health related to cancer prevention, cancer screening, and the health and wellness of cancer survivors.[9] Moreover, some have argued that persistent racial and ethnic disparities in cancer and other health outcomes cannot be eliminated without addressing the fundamental causes for these disparities: socioeconomic status and racism.[12, 16] A recent review of the complex relationship between various forms of racism and health called for more research on interventions to mitigate the impact of racism on health.[21]

Purpose

The purpose of this NOFO is to conduct evaluation research to build an evidence base of innovative, community-based, structural interventions across multiple social determinants of health to reduce racial and ethnic disparities in cancer outcomes. The purpose will be achieved through three (3) components.

> **Component A: Primary Cancer Prevention** – evaluation of the implementation, impact, and causal mechanisms of an intervention's effect to reduce racial or ethnic inequities in cancer risk at the population level.
>
> **Component B: Cancer Screening** – evaluation of the implementation, impact, and causal mechanisms of an intervention's effect to reduce racial or ethnic inequities in the receipt of appropriate screening services for breast, cervical, colorectal or lung cancer.
>
> **Component C: Health and Wellbeing of Cancer Survivors**– evaluation of the implementation, impact, and causal mechanisms of an intervention's effect to reduce racial or ethnic inequities in the health and wellbeing of cancer survivors.

Healthy People 2030 and other National Strategic Priorities

This research NOFO supports Healthy People 2030 (https://health.gov/healthypeople) [34] objectives within multiple topic areas. This NOFO will support the cancer goal to reduce the number of new cancer cases, as well as illness, disability, and death caused by cancer. The specific cancer objectives supported under this topic include:

C-3 Increase the proportion of adults who receive a lung cancer screening based on the most recent guidelines
C-5 Increase the proportion of females who receive a breast cancer screening based on the most recent guidelines
C-7 Increase the proportion of adults who receive a colorectal cancer screening based on the most recent guidelines
C-9 Increase the proportion of females who receive a cervical cancer screening based on the most recent guidelines
C-RO1 Increase the mental and physical health-related quality of life for cancer survivors

In addition, this NOFO supports the Healthy People 2030 focus on social determinants of

health. Although Healthy People 2030 identifies discrimination as a key issue within the social determinants of health, no measurable objectives are included to address systemic racism, an aim of the NOFO. The objectives related to this NOFO that address additional social determinants of health include:

NWS-01 Reduce household food insecurity and hunger
EH-06 Reduce the amount of toxic pollutants released into the environment
PA-10 Increase the proportion of adults who walk or bike to get places
SDOH-01 Reduce the proportion of people living in poverty
SDOH-02 Increase employment in working-age people
HC/HIT-R01 Increase the health literacy of the population

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) seeks to achieve health equity through multisectoral and multilevel collaboration on the social determinants of health.[35] This research NOFO will support NCCDPHP work in these priority areas:

- **Built environment**: human-made surroundings where people live, learn, work, play, worship and age that influence overall community health and individual behaviors that drive health. A healthy built environment facilitates access to transportation and physical resources that enhance quality of life, minimizes exposure to environmental contaminants, and supports physical activity, safe recreation, a safe workplace, and other protective factors.
- **Community-clinical linkages**: connections made among health care systems and services, public health agencies, and community-based organizations to improve population health. Effective community-clinical linkages improve cancer outcomes by increasing access to and utilization of preventive and chronic care services in local communities.
- **Social connectedness**: the degree to which individuals or groups of individuals have a desired number, quality, and diversity of relationships that create a sense of belonging and being cared for, valued, and supported. A high degree of social connectedness can increase the likelihood of individuals engaging in positive health behaviors, ultimately improving health outcomes by moderating the negative health effects of adversities such as stress, trauma, adversity, anxiety, and depression. Social connectedness can create opportunities to access resources that might otherwise be unavailable. In addition, social connectedness can contribute to collective efficacy to change policy, programs, and social norms.

Public Health Impact

This NOFO will generate evidence on interventions to reduce cancer-related disparities by race and ethnicity by implementing and evaluating community-based efforts to improve cancer outcomes through structural changes in social determinants of health. Rigorous evaluation research will advance our understanding of what works, for whom and why.[24] This research will fill important gaps in knowledge about 1) the implementation and potential for scaling of innovative interventions to reduce racial and ethnic disparities in cancer outcomes, 2) the resources required for implementation and scaling, and 3) the impact of novel community-based approaches to reduce health inequities and improve cancer-related outcomes in economically or

socially disadvantaged populations. In addition, the evaluation research will contribute to an underlying theory of causation or reveal specific elements and strategies that contribute to intervention effectiveness.

Relevant Work

None

2. Approach

There are three separate components to this NOFO. *Applicants may apply for **one** of the following components: Component A: Primary Cancer Prevention, Component B: Cancer Screening, or Component C: Health and Wellbeing of Cancer Survivors. The application should clearly indicate which Component is being applied for.*

Applicants should propose rigorous evaluation research of an on-going intervention, expanded as needed, to generate evidence about cancer prevention and control strategies that involve structural/systemic changes in social determinants of health (see lower tiers of the impact pyramid in Section1.1 Background and Purpose), including systemic racism. The research is expected to go beyond measures of effectiveness to address theories of causation and issues of implementation and adaptation for well-defined racial or ethnic minority populations under specific community contexts.

Systemic racism describes the accumulation and incorporation of long-standing racialized practices into social and economic structures. Systemic racism is broadly used in this NOFO to capture the related concepts of structural racism and institutional racism.[36, 37] Interventions should be community-based and address 1) systemic racism; and 2) one or more of the following: the built environment; community-clinical linkages; and social connectedness.

For this NOFO, the following definitions apply:

1. Built environment is broadly defined to include physical structures, the advertising environment, the distribution of community institutions and services, and the workplace.
2. Community-clinical linkages are defined as connections made among health care systems and services, public health agencies, agencies from other sectors, and community-based organizations, as well as efforts to promote inclusion and diversity in the clinical setting, to improve population health.
3. Social connectedness is the degree to which an individual or group of individuals are socially close, interrelated, or share resources with each other [38], and it is related to social isolation.[39] Social connectedness applies broadly to include the related concept of social capital, networks of relationships within and across communities that are a source of shared group resources and benefits to individuals.[40] These networks can be strengthened to expand their power and influence and, therefore, contribute to the collective efficacy needed to change policies, programs, and social norms to improve health.[41,42]

Applicants are encouraged to be innovative and opportunistic. For example, novel interventions to address systemic inequities, when carefully investigated, could serve as a natural experiment to inform future public health practice. Multi-sector and multilevel interventions are encouraged. The NOFO is not intended to fund evaluations of interventions that involve only

counseling and education (see top of the impact pyramid in Section 1.1 Background and Purpose), but multi-level interventions could include this element.

For all components, this evaluation research could involve nonrandomized studies with rigorous attention to comparability and bias (quasi-experimental research). Depending on the complexity of the intervention strategies to be evaluated, multiple and mixed methods could be employed, such as an examination of large data sets combined with case studies, and various types of evaluation analyses.

Applicants under each component are expected to identify and engage key community partners from relevant sectors and community residents from the racial or ethnic minority groups of focus to participate throughout the research process.

Objectives/Outcomes

Component A: Primary Cancer Prevention – to conduct evaluation research on an innovative, community-based intervention to reduce cancer risk in one or more racial or ethnic minority populations who experience disproportionate exposure to cancer risk factors. This research will assess the implementation, impact, and causal mechanisms of the intervention's effect to reduce cancer risk at the population level. Research in this component will build the evidence base for community-based interventions for reduced cancer incidence at the population-level (primary cancer prevention) among racial and ethnic minority populations.

1. Generate evidence regarding the effectiveness of a multi-factor community-based intervention focused on the built environment to reduce exposures to carcinogens or change cancer-related health behaviors to reduce cancer risk and/or social connectedness to increase the adoption of healthy behaviors and influence on policies, programs and social norms associated with lower cancer risk.
2. Generated evidence regarding the impact of addressing systemic racism on the effectiveness of the intervention focused on one or more racial and ethnic minority populations.
3. Inform the theory of causation underlying the different elements of the intervention.
4. Determine challenges in implementation and adaptation for one or more racial and ethnic minority groups in a specific setting and make recommendations for challenges to be addressed when repeating or scaling the intervention.

Recipient is expected to:

- Select a promising, on-going intervention being implemented in a community that focuses on the built environment and/or social connectedness to reduce cancer risk among people from one or more racial or ethnic minority groups. The intervention should be informed by evidence that suggests the proposed approach, which could involve influencing policies, programs or social norms, could result in change in exposures to carcinogens or cancer-related health behaviors within the study period. The original purpose of the intervention need not be cancer prevention, provided the intended outcomes include reduced carcinogenic exposures or changes in behaviors that lead to reduced cancer risk. Interventions that address multiple or clusters of cancer risk factors (exposures and/or health behaviors) are encouraged. The intervention should not

include: 1) chemo-preventive agents, drugs, or nutritional supplements of any kind; 2) vaccines; 3) prophylactic surgery; or 4) screening tests for cancer or pre-cancer conditions.

- Use an evidence-based theoretical framework of causation to address systemic racism.
- Expand the intervention population, as needed, to achieve a sufficiently large number of persons within a well-defined racial or ethnic minority group to allow findings to be generated for that group and yield stable estimates of intervention effects. A power analysis should be used to demonstrate that the proposed sample size is adequate to detect an intervention effect within the study period.
- Anticipate, identify, and address problems in the implementation of the project in a transparent and timely manner.
- Implement the multi-factor intervention, in collaboration with the entity implementing the original, on-going intervention and other community partners.
  Conduct an evaluation research study to assess the effectiveness of the intervention overall and the core elements of the intervention. The primary outcomes should be measures of exposures or health behaviors.
- Examine research questions within a framework of causal mechanisms of effectiveness.
- Assess factors that serve as barriers or facilitators for successful implementation and adaptation.
- Convene a Community Advisory Board that includes representatives of key community partners, government agencies, nonprofit organizations, and community residents that meets at least semi-annually to provide input and discuss progress and challenges. This board should include members who provide testing or other services to the population of focus related to the cancer risk factor, if the intervention relies on such services.
- Analyze and disseminate study findings to public health audiences, community partners and residents, and other persons who may be interested in applying the study findings.
- Prepare a final report that includes recommendations for translation, adaptation, scaling and sustaining the intervention focused on one or more racial or ethnic minority groups under specific community contexts.
- Develop multiple manuscripts for publication in the scientific literature that present project findings and provide insights for adaptation and scaling.
- Prepare a budget that includes travel costs for up to four people, including the PI, for annual meetings with CDC staff in the first Budget Period and in annual continuation plans and budgets. Funds may be used to cover reasonable, actual out-of-pockets costs incurred by Community Advisory Board members, as a result of attending scheduled meetings, and incentives for members who are not participating in meetings as part of their normal job duties.
- Participate on monthly calls with CDC staff to discuss project progress, accomplishments and challenges.

Component B: Cancer Screening – to conduct evaluation research on an innovative, multi-sector intervention to reduce inequities in the receipt of appropriate screening and follow-up services for breast, cervical, colorectal or lung cancer (on-time initial screening, routine re-screening at recommended intervals, and appropriate follow-up after inconclusive/incomplete screening and abnormal test results) among one or more racial or ethnic populations who

experience disparities in cancer screenings. This research will generate knowledge about the implementation, impact, and causal mechanisms of the intervention's effect on the cancer screening outcomes. Research in this component will also build the evidence base for community-based, structural interventions on social determinants to decrease racial and ethnic disparities in the receipt of recommended cancer screening services.

1. Generate evidence regarding the effectiveness of a multi-factor community-based intervention focused on the built environment and/or community-clinical linkages to increase the receipt of appropriate cancer screening services.
2. Generate evidence regarding the impact of addressing systemic racism on the effectiveness of the intervention focused on one or more racial and ethnic minority populations.
3. Inform the theory of causation underlying the different elements of the intervention.
4. Determine challenges in implementation and adaptation for one or more racial and ethnic minority groups in a specific setting and make recommendations for challenges to be addressed when repeating or scaling the intervention.

Recipient is expected to:

- Select a promising, on-going community-based intervention to improve the use of, and follow up for, one or more cancer screening tests as recommended in one or more racial or ethnic minority groups. The intervention should focus on one or more cancer screening tests with A or B recommendations from the U.S. Preventive Services Task Force: breast [43], colorectal [44], cervical [45], or lung cancer [46] and involve community-clinical linkages, and/or the built environment. An intervention that does not have cancer screening as its primary purpose may be studied, but the intervention should address one or more known barriers to cancer screening and be reasonably expected to improve cancer screening outcomes. Costs associated with the provision of medical services are not supported by this NOFO.
- Use an evidence-based theoretical framework to address systemic racism.
- Expand the intervention population, as needed, to achieve a sufficiently large number of persons within one or more racial or ethnic minority groups to allow findings to be generated for that group. A power analysis should be used to demonstrate that the proposed sample size is adequate to detect an intervention effect within the study period.
- Anticipate, identify, and address problems in the implementation of the project in a transparent and timely manner.
- Implement the multi-factor intervention, in collaboration with the entity implementing the original, on-going intervention and other community partners.
- Conduct an evaluation research study to assess the effectiveness of the intervention overall and the core elements of the intervention. Consider all relevant outcomes across the screening continuum, including on-time initial screening, routine re-screening at recommended intervals, appropriate follow-up after inconclusive/incomplete screening, and follow up and treatment initiation after a positive test.
- Examine research questions within a framework of causal mechanisms of effectiveness.
- Convene a Community Advisory Board that includes representatives of key community partners (including health care providers who provide screening services to the

community), government agencies, nonprofit organizations, and community residents that meets at least semi-annually to provide input and discuss progress and challenges.
- Assess factors that serve as barriers and facilitators for successful implementation and adaptation.
- Analyze and disseminate study findings to public health audiences, community partners and members, and other persons who may be interested in applying the study findings.
- Prepare a final report that includes recommendations for translation, adaptation, scaling and sustaining the intervention focused on one or more racial or ethnic minority groups under specific community contexts.
- Develop multiple manuscripts for publication in the scientific literature that present project findings and provide insights for adaptation and scaling.
- Prepare a budget that includes travel costs for up to four people, including the PI, for annual meetings with CDC staff in the first Budget Period and in annual continuation plans and budgets. Funds may be used to cover reasonable, actual out-of-pockets costs incurred by Community Advisory Board members, as a result of attending scheduled meetings, and incentives for members who are not participating in meetings as part of their normal job duties.
- Participate on monthly calls with CDC staff to discuss project progress, accomplishments and challenges.

Component C: Health and Wellbeing of Cancer Survivors – to conduct evaluation research to address barriers to health and well-being among adult cancer survivors from one or more racial or ethnic minority populations who experience disparities in mental or physical health after a cancer diagnosis. This research will generate knowledge about the implementation, impact, and causal mechanisms of the intervention's effect on the health and wellbeing of cancer survivors. Research in this component will build the evidence base to support policies to assist cancer survivors from racial and ethnic minority groups to lead productive, healthy lives.

1. Generate evidence regarding the effectiveness of a multi-factor community-based intervention focused on the built environment and/or social connectedness and/or community-clinical linkages to improve the health and well-being of cancer survivors.
2. Generate evidence regarding the impact of addressing systemic racism on the effectiveness of the intervention focused on one or more racial and ethnic minority populations.
3. Inform the theory of causation underlying the different elements of the intervention.
4. Determine challenges in implementation and adaptation for one or more racial and ethnic minority groups in a specific setting, and make recommendations for challenges to be addressed when repeating or scaling the intervention.

Recipient is expected to:

- Select a promising, on-going community-based intervention focused on community-clinical linkages and/or the built environment and/or social connectedness to address one or more known barriers to health and wellbeing among survivors of adult cancers from one or more racial or ethnic minority groups. Costs associated with the provision of medical services are not supported by this NOFO. The intervention outcomes of interest

should include one or more of the following:
    - reduced barriers to healthy behaviors;
    - improved access to recommended preventive health services and behavioral counseling;
    - reduced financial toxicity from recurring medical care costs;
    - improved management, reduction or elimination of co-occurring chronic conditions such as diabetes and obesity;
    - reduced barriers to returning to/remaining at work;
    - improved quality of mental and physical health-related quality of life.
- Use an evidence-based theoretical framework to address systemic racism.
- Expand the intervention population, as needed, to generate evidence about the effectiveness of this intervention and generate stable estimates of outcome measures for cancer survivors from one or more racial or ethnic minority groups. A power analysis should be used to demonstrate that the proposed sample size is adequate to detect an intervention effect within the study period.
- Implement the multi-factor intervention, in collaboration with the entity implementing the original, on-going intervention and other community partners.
- Conduct an evaluation research study to assess the effectiveness of the intervention overall and the core elements of the intervention.
- Examine research questions within a framework of causal mechanisms of effectiveness.
- Convene a Community Advisory Board that include representatives of key community partners (including health care providers for cancer survivors in the community), government agencies, nonprofit organizations, and cancer survivors who are community residents that meets at least semi-annually to provide input and discuss progress and challenges.
- Assess factors that serve as barriers or facilitators for the successful implementation and adaptation.
- Analyze and disseminate study findings to public health audiences, community partners and members, and other persons who may be interested in applying the study findings.
- Prepare a final report that includes recommendations for translation, adaptation, scaling and sustaining the intervention focused on one or more racial or ethnic minority groups under specific community contexts.
- Develop multiple manuscripts for publication in the scientific literature that present project findings and provide insights for adaptation and scaling.
- Prepare a budget that includes travel costs for up to four people, including the PI, for annual meetings with CDC staff in the first Budget Period and in annual continuation plans and budgets. Funds may be used to cover reasonable, actual out-of-pockets costs incurred by Community Advisory Board members, as a result of attending scheduled meetings, and incentives for members who are not participating in meetings as part of their normal job duties.
- Participate on monthly calls with CDC staff to discuss project progress, accomplishments, and challenges.

Target Population

Component A: Primary Cancer Prevention - The intervention should be designed to address

the needs of people from one or more racial or ethnic minority groups who experience disparities in cancer incidence, exposure to carcinogens, or the prevalence of cancer-related health behaviors. The intervention population should be persons without a personal history of cancer and span multiple age groups, consistent with a lifespan approach to cancer prevention. The age range of the population of focus should not be limited to children.

Component B: The intervention should be designed to address the needs of people from one or more racial or ethnic minority groups who experience disparities in cancer screening. The population of focus should be adults without a personal history of the cancer being screened for and not known to be at high risk of cancer. The age range of the intervention population should include the ages for which the selected cancer screening test is currently recommended by the U.S. Preventive Services Task Force (USPSTF).[43-46]

Component C: Cancer Survivors - The intervention should be designed to address the needs of people from one or more racial or ethnic minority groups who experience disparities in health outcomes after a cancer diagnosis. The intervention population should be adults with a personal history of adult-onset cancer of any type (other than non-melanoma skin cancer) who have completed initial course of treatment with the intent to cure but may be continuing long-term hormonal treatment. Most of the intervention population should fall within the age range of 45-84 years.

Collaboration/Partnerships

Component A: Primary Cancer Prevention, Component B: Cancer Screening, and Component C: Health and Wellbeing of Cancer Survivors

Investigators are expected to build on and expand collaborations and partnerships with researchers or agencies (e.g., community health clinics, cancer centers, community-based organizations, nonprofits, local governments, employers) that have interests in reducing cancer disparities, or that do not have established interests but nonetheless may influence key levers in reducing cancer disparities (such as influencing the availabilities of resources within communities). Such relationships could be useful for planning and/or implementation of their evaluation research plans. Applicants are expected to engage community residents with a commitment to reducing disparities, for instance, residents from the targeted population, in their research process (including planning and implementation).

Evaluation/Performance Measurement

Component A: Primary Cancer Prevention, Component B: Cancer Screening, and Component C: Health and Wellbeing of Cancer Survivors

Applicants should submit an evaluation plan with key dates and milestones for the first year of the project. In subsequent funded years, evaluation is expected to include assessment of the degree to which the research fills important research gaps related to advancing health equity for cancer prevention and control.

Translation Plan

Component A: Primary Cancer Prevention, Component B: Cancer Screening, and Component C: Health and Wellbeing of Cancer Survivors

At the start of the final project year, awardees are expected to submit plans for presenting findings to CDC, at professional meetings, at formal briefings for health and policy makers, and to the community residents where the intervention was implemented, highlighting opportunities for policy, environmental, and system changes (the lower tiers of the impact pyramid in Section 1.1 Background and Purpose). One or more reports of findings and recommendations for implementing, translating, adapting or scaling the intervention are expected to be submitted to peer-reviewed journals and disseminated through diverse media such as a study website, guidelines, toolkits, and policy briefs.

OMB/PRA: OMB/PRA is not expected to apply

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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: $15,000,000

The estimated total funding (direct and indirect) for the five-year period of performance, September 30, 2021 to September 29, 2026 is $15,000,000 to fund three (3) awards in three

Components.

Component A: Primary Cancer Prevention
Number of Awards: 1
Estimated Funding: $5,000,000

Component B: Cancer Screening
Number of Awards: 1
Estimated Funding: $5,000,000

Component C: Health and Wellbeing of Cancer Survivors
Number of Awards: 1
Estimated Funding: $5,000,000

Anticipated Number of Awards: 3

If an applicant requests a funding amount greater than the $1,000,000 ceiling for the first year, HHS/CDC will consider the application non-responsive and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

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.

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

Award ceiling and floor are for the first 12-month budget period only.

Award Ceiling:	$1,000,000 Per Budget Period
Award Floor:	$0 Per Budget Period
Total Period of Performance Length:	5 year(s)

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

HHS/CDC grants policies as described in the HHS Grants Policy Statement (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
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:

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

Hispanic-serving Institutions
Historically Black Colleges and Universities (HBCUs)
Tribally Controlled Colleges and Universities (TCCUs)
Alaska Native and Native Hawaiian Serving Institutions

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government
U.S. Territory or Possession

Other:

Faith-based or Community-based Organizations
Regional Organizations
Bona Fide Agents: A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms."
Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to https://gov.ecfr.io/cgi-bin/searchECFR

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

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

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

3. Additional Information on Eligibility

None

4. Justification for Less than Maximum Competition

Not applicable

5. Responsiveness

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

Applicants may only apply for one (1) Component of funding (Component A, or Component B, or Component C).

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://cage.dla.mil/
- 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/index.html .
- 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) is allowed. 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.

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-f/general-forms-f.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: **01/11/2021**
Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CIO staff to estimate the

potential review workload and plan the review.

By the date listed above and in Part 1. Overview Information, 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
- Component

The letter of intent should be emailed to Sue Shaw at zgx7@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-f/general-forms-f.pdf and http://grants.nih.gov/grants/how-to-apply-application-guide.htm 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-f/general-forms-f.pdf and here: http://grants.nih.gov/grants/how-to-apply-application-guide.htm must be followed along with any additional instructions provided in the NOFO.
Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.
The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:
• A description of the data to be collected or generated in the proposed project;
• Standards to be used for the collected or generated data;
• Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of
provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights -
this section should address access to identifiable and de-identified data);
• Statement of the use of data standards that ensure all released data have appropriate documentation that
describes the method of collection, what the data represent, and potential limitations for use; and
• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation
and access are not justified (this section should address archiving and preservation of identifiable and deidentified
data).
Examples of DMPs may be found here: USGS, http://www.usgs.gov/products/data-and-tools/data-management/data-management-plans

RESEARCH PLAN

The applicant?s research plan should address activities that will be conducted over the entire 5-year period of performance and should include the following items:

Component A: Primary Prevention

Study Setting and Context

- Describe the racial or ethnic disparity in cancer risk to be addressed; for example, which cancer risk factors in which racial or ethnic minority groups will be addressed by the intervention.
- Describe previous efforts to address these cancer risks factors within the racial or ethnic minority groups of focus and the remaining knowledge gaps.
- Describe the aspects of the built environment and/or social connectedness to be addressed by the intervention and how these aspects of the built environment and/or social connectedness are related to the prevalence of the cancer risk factors in the population of focus.
- Explain where evidence is lacking on the intervention to be evaluated.
- Describe how systemic racism will be addressed by the intervention and how systemic racism is related to the prevalence of the cancer risk factors in the population of focus.
- Describe the geographic area(s) or communities for the proposed evaluation research and the size and demographic characteristics of the populations included in the proposed evaluation research study.
- Describe the history of the on-going community intervention, the entity implementing the intervention, and its original aims and scope, and how the intervention will be expanded for this evaluation research project.
- Describe existing relationships, if any, between the research team and key community partners.
- Describe the potential value of the proposed intervention for policy, environmental or systems change to reduce cancer risk for people from the racial or ethnic minority groups of focus.

Study Methods

- Provide the hypotheses to be tested related to implementation, causal mechanisms, and intervention effectiveness to reduce population-level cancer risk.
- Describe the desired changes in exposures to carcinogens or cancer-related health behaviors from the intervention and how they will be measured.
- Describe key sources of data on outcome measures, including existing datasets and data systems that permit the assessment of the impact of the intervention, and plans for original data collection.
- Provide a data analysis plan including statistical methods, sample sizes and power calculations.
- Describe how study data will be analyzed using appropriate statistical methods to determine the efficacy of the intervention.
- Describe and provide power analyses conducted to determine the appropriate sample size for evaluating the intervention in the population of focus. The study should be powered to detect change in measures of carcinogen exposure or measures of cancer-related health behaviors.

Study Dissemination and Impact

- Describe plans for disseminating study findings at professional meetings, at formal briefings for health and policy makers, and to the community residents where the intervention was implemented.
- Describe plans for the submission of findings and recommendations for translating, adapting or scaling the intervention for publication in peer-reviewed journals and other venues to inform future policy, environmental or systems change to reduce racial and ethnic disparities in cancer incidence.

Staffing and Management

- Provide a staffing and management plan that defines the roles, responsibilities, and qualifications of team and expected contributions of key/collaborative partners.
    - The Research Team: The applicant should describe the experience of the principal investigator and co-investigators in undertaking complex evaluation research studies that (a) engage community representatives as partners; (b) are multi-level or multi-sector (c) involve partner collaboration throughout the study process; (d) result in peer-reviewed journal publications; and (e) provide decision-support for public and private decision makers.
    - The Principal Investigator: The applicant should describe the principal investigator?s (a) expertise in primary cancer prevention; (b) experience, if any, working with people from racial and ethnic minority groups to address systemic racism; (c) established leadership in designing, implementing and evaluating community-based interventions, (d) track record of publishing study findings in peer-reviewed journals and making presentations at professional and scientific conferences, and policy forums; (e) his/her commitment to engage community residents and organizations as partners and (f) the amount of time allocated by the PI to this research program.
    - Other Researchers: For each proposed co-investigator and other members of the research team, the applicant should (a) describe the person?s expertise and role on the proposed project; (b) describe previous experience and contributions to research on relevant topics; and (c) specify the amount of time that will be committed to this research program.
- Provide a management plan, which describes:
    - the staffing plan for the 5-year period of performance. Include project organizational charts with key personnel.
    - how and by whom the quality oversight and supervision will be provided for the research team.
    - the amount of time each person will devote to the project.
    - If a position is yet to be filled, provide the position description and proposed timeline to fill the position in an appendix.
- Describe the composition and role of the Community Advisory Board.
- Provide a detailed timeline including realistic and measurable milestones for proposed project activities and include a budget plan that is linked to activities and milestones.
- Describe plans for producing technical reports, professional presentations,

communications to community partners and others who may be interested in the study findings, and journal and other publications.
- Provide a letter of commitment from partner organizations who will be involved in the activities proposed in the application. Letters should (a) describe prior collaborations with the applicant organization, if any; and (b) specify the contributions that the partner organization is committed to make to the proposed research, including the provision of necessary data.
- Provide a detailed budget and line-item justification for the first year that is consistent with the stated objectives. Applicants should also provide budget estimates for each of the other Budget Periods.

Component B: Cancer Screening

Study Setting and Context

- Describe the racial or ethnic disparity in cancer screening to be addressed; for example, which USPSTF recommended cancer screening(s) among people from which racial or ethnic minority groups will be the focus of the intervention.
- Describe previous efforts to address disparities in the selected cancer screening within disproportionately affected racial or ethnic populations and the remaining knowledge gaps.
- Describe the aspects of built environment and community-clinical linkages to be addressed by the intervention and how these aspects are related to cancer screening in the population of focus.
- Explain where evidence is lacking on the intervention to be evaluated.
- Describe the aspects of systemic racism to be addressed by the intervention and how racism affects cancer screening in the population of focus.
- Describe the history of the on-going community intervention, the entity implementing the intervention, its original aims and scope, and how the intervention will be expanded for this evaluation research project.
- Describe the geographic area(s) or communities for the proposed evaluation research and the size and demographic characteristics of the populations included in the proposed evaluation research study.
- Describe existing relationships, if any, between the research team and key community partners.
- Describe the potential value of the proposed intervention for policy, environmental or systems change to improve cancer screening outcomes for people from the racial or ethnic minority groups of focus.

Study Methods

- Provide the hypotheses to be tested related to implementation, causal mechanisms, and intervention effectiveness to improve cancer screening outcomes.
- Describe the desired changes in screening outcomes and how they will be measured.
- Describe key sources of data on outcome measures, including existing datasets and data systems that permit the assessment of the impact of the intervention on cancer screening

outcomes, and plans for original data collection.

- Provide a data analysis plan including statistical methods, sample sizes and power calculations.
- Describe how study data will be analyzed using appropriate statistical methods to determine the efficacy of the intervention.
- Describe and provide power analyses conducted to determine the appropriate sample size for evaluating the intervention in the population of focus. The study should be powered to detect change in key screening continuum outcomes.

Study Dissemination and Impact

- Describe plans for disseminating study findings at professional meetings, at formal briefings for health and policy makers, and to the community residents where the intervention was implemented.
- Describe plans for the submission of findings and recommendations for translating, adapting or scaling the intervention for publication in peer-reviewed journals and other venues to inform future policy, environmental or systems change to reduce racial and ethnic disparities in cancer screening.

Staffing and Management

- Provide a staffing and management plan that defines the roles, responsibilities, and qualifications of team and expected contributions of key/collaborative partners.
    - The Research Team: The applicant should describe the experience of the principal investigator and co-investigators in undertaking complex evaluation research studies that (a) engage community representatives as partners; (b) are multilevel or multi-sector (c) involve partner collaboration throughout the study process; (d) result in peer-reviewed journal publications; and (e) provide decision-support for public and private decision makers.
    - The Principal Investigator: The applicant should describe the principal investigator?s (a) expertise in cancer screening; (b) experience, if any, working with people from the racial and ethnic minority groups to address systemic racism; (c) established leadership in designing, implementing and evaluating community-based interventions, (d) track record of publishing study findings in peer-reviewed journals and making presentations at professional and scientific conferences, and policy forums; (e) his/her commitment to engage community residents and organizations as partners and (f) the amount of time allocated by the PI to this research program.
    - Other Researchers: For each proposed co-investigator and other members of the research team, the applicant should (a) describe the person?s expertise and role on the proposed project; (b) describe previous experience and contributions to research on relevant topics; and (c) specify the percentage of time that will be committed to this research program.
- Provide a management plan, which describes:
    - the staffing plan for the 5-year period of performance. Include project organizational charts with key personnel.

    - how and by whom the quality oversight and supervision will be provided for the research team.
    - the amount of time each person will devote to the project.
    - If a position is yet to be filled, provide the position description and proposed timeline to fill the position in an appendix.
- Describe the composition and role of the Community Advisory Board.
- Provide a detailed timeline including realistic and measurable milestones for proposed project activities and include a budget plan that is linked to activities and milestones.
- Describe plans for producing technical reports, professional presentations, communications to community partners and others who may be interested in the study findings, and journal and other publications.
- Provide a letter of commitment from partner organizations who will be involved in the activities proposed in the application. Letters should (a) describe prior collaborations with the applicant organization, if any; and (b) specify the contributions that the partner organization is committed to make to the proposed research, including the provision of necessary data.
- Provide a detailed budget and line-item justification for the first year that is consistent with the stated objectives. Applicants should also provide budget estimates for each of the other Budget Periods.

Component C: Health and Wellbeing of Cancer Survivors

Study Setting and Context

- Describe the racial or ethnic disparity in health and wellbeing after a cancer diagnosis to be addressed; for example, the intervention will address which aspects of health and wellbeing among survivors of which adult cancers in which racial or ethnic minority groups.
- Describe previous efforts, if any, to address disparities in health and wellbeing among cancer survivors within the racial or ethnic minority populations of focus and the remaining knowledge gaps.
- Describe the aspects of the built environment and/or community-clinical linkages to be addressed by the intervention and how these are related to health and wellbeing among the identified population of cancer survivors.
- Explain how the intervention to be evaluated is lacking sufficient evidence.
- Describe the aspects of systemic racism to be addressed by the intervention and how racism affects health and wellbeing in the target population of cancer survivors.
- Describe the history of the on-going community intervention, the entity implementing the intervention and its original aims and scope, and how the intervention will be expanded for this evaluation research project.
- Describe the geographic area(s) or communities for the proposed evaluation research and the size and demographic characteristics of the populations included in the proposed evaluation research study.
- Describe existing relationships, if any, between the research team and key community partners.

- Describe the potential value of the proposed intervention for policy, systems changes, community changes to improve health and wellbeing among cancer survivors from the racial or ethnic minority populations of focus.

Study Methods

- Provide the hypotheses to be tested related to implementation, causal mechanisms, and intervention effectiveness to improve health and wellbeing among cancer survivors.
- Describe the desired changes in health outcomes and how they will be measured.
- Describe key sources of data on outcome measures, including existing datasets and data systems that permit the assessment of the impact of the intervention on health outcomes, and plans for original data collection.
- Provide a data analysis plan including statistical methods, sample sizes and power calculations.
- Describe how study data will be analyzed using appropriate statistical methods to determine the efficacy of the intervention.
- Describe and provide power analyses conducted to determine the appropriate sample size for evaluating the intervention in the population of focus. The study should be powered to detect change in key intervention outcomes.

Study Dissemination and Impact

- Describe plans for disseminating study findings at professional meetings, at formal briefings for health and policy makers, and to the community residents where the intervention was implemented.
- Describe plans for the submission of findings and recommendations for translating, adapting or scaling the intervention for publication in peer-reviewed journals and other venues to inform future policy, environmental or systems change to reduce racial and ethnic disparities in health and wellbeing after a cancer diagnosis.

Staffing and Management

- Provide a staffing and management plan that defines the roles, responsibilities, and qualifications of team and expected contributions of key/collaborative partners.
    - The Research Team: The applicant should describe the experience of the principal investigator and co-investigators in undertaking complex evaluation research studies that (a) engage community representatives as partners; (b) are multilevel or multi-sector (c) involve partner collaboration throughout the study process; (d) result in peer-reviewed journal publications; and (e) provide decision-support for public and private decision makers.
    - The Principal Investigator: The applicant should describe the principal investigator?s (a) expertise in cancer survivorship; (b) experience, if any, working with people from the racial and ethnic minority groups to address systemic racism; (c) established leadership in designing, implementing and evaluating community-based interventions, (d) track record of publishing study findings in peer-reviewed journals and making presentations at professional and scientific conferences, and policy forums; (e) his/her commitment to engage

community residents and organizations as partners and (f) the amount of time allocated by the PI to this research program.
    - Other Researchers: For each proposed co-investigator and other members of the research team, the applicant should (a) describe the person?s expertise and role on the proposed project; (b) describe previous experience and contributions to research on relevant topics; and (c) specify the amount of time that will be committed to this research program.
- Provide a management plan, which describes:
    - the staffing plan for the 5-year period of performance. Include project organizational charts with key personnel.
    - how and by whom the quality oversight and supervision will be provided for the research team.
    - the amount of time each person will devote to the project.
    - If a position is yet to be filled, provide the position description and proposed timeline to fill the position in an appendix.
- Describe the composition and role of the Community Advisory Board.
- Provide a detailed timeline including realistic and measurable milestones for proposed project activities and include a budget plan that is linked to activities and milestones.
- Describe plans for producing technical reports, professional presentations, communications to community partners and others who may be interested in the study findings, and journal and other publications.
- Provide a letter of commitment from partner organizations who will be involved in the activities proposed in the application. Letters should (a) describe prior collaborations with the applicant organization, if any; and (b) specify the contributions that the partner organization is committed to make to the proposed research, including the provision of necessary data.
- Provide a detailed budget and line-item justification for the first year that is consistent with the stated objectives. Applicants should also provide budget estimates for each of the other Budget Periods.

6. Appendix

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

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 35 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.
CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general-forms-f.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

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

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

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

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

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

    a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.
    b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **02/10/2021**

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.

11. Funding Restrictions

Expanded Authority:
For more information on expanded authority and pre-award costs, go to https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf and speak to your GMS.
All HHS/CDC awards are subject to the federal regulations, 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.

Protecting Life in Global Health Assistance:
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/additional-requirements/ar-35.html).

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

> **Data Management Plan:**
> Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.
> Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).

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

Human Subjects:
Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions.
If the proposed research project involves more than one institution and will be conducted in the United States, awardees are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and include a single IRB plan in the application, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy or a compelling justification based on ethical or human subjects protection issues or other well-justified reasons is provided. Exceptions will be reviewed and approved by CDC in accordance with Department of Health and Human Services (DHHS) Regulations (Title 45 Code of Federal Regulations Part 46), or a restriction may be placed on the award. For more information, please contact the scientific/research contact included on this NOFO.
Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in CDC-funded, cooperative research studies are not expected to follow

the requirement for sIRB.

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. For more information on expanded authority and pre-award costs, go to: (http://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).

Awardees 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: Additional Requirement 25 | Additional Requirements | Grants

Funds will be restricted until:

- IRB and OMB/PRA (if needed) approvals are obtained. IRB approval letters must be dated and should specify the name of the NOFO or title of the project covered and the expiration date or lack of need for continuation review. If and when new supplements are added to the protocol, dated IRB approval letters for protocol amendments are required. If the amendment approval letter does not specify the content of the amendment, a summary of the amendment request that was submitted to the IRB is required.

- Human subjects education requirement documentation is provided for any new key personnel or other significant contributors involved in the design or conduct or research involving human subjects.

- Awardee organizations that rely on other institutions for their IRB review responsibilities shall provide documentation of the reliance and the IRB approval. A sample written agreement is available at https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html

Applicants are advised that any activities involving standard information collection (i.e., surveys, questionnaires, data requests, etc.) from 10 or more non-federal individual/entities are

subject to Paperwork Reduction Act (PRA) requirements and may require the CDC to coordinate an OMB/PRA approval request).

Reimbursement of pre-award costs is allowed. All HHS/CDC awards are subject to the terms and conditions, cost principles, 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.

For more information on expanded authority and pre-award costs, go to: http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf or speak with your Grants Management Specialist (GMS).

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. Upload the questionnaire and supporting documents as an attachment in the "12. Other Attachments" section of the "RESEARCH & RELATED Other Project Information" section of the application. 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 (https://grants.nih.gov/grants/how-to-apply-application-guide.html).

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 (https://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?

Additional questions for Components A, B, C:

- What is the potential impact of the research on reducing the identified racial or ethnic disparities in cancer outcomes?
- Will the work lead others to investigate the problem, open new areas of research, or change the scientific approach or public health practice, and how this will improve and be of value to public health?

- If successful, does the intervention have the potential to be sustainable?
- If successful, do the research results/intervention have the potential to be sustainable?

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?

Additional questions for Components A, B, and C:

- Do investigators have successful experience with community-based intervention research?
- Do investigators demonstrate successful experience working with populations similar to the target population?
- Is there evidence of past collaborations with the proposed research team and key partners and potential users of the study findings?
- Does the PI time and other key staff time on the project seem adequate to carry out the work?

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?

Additional questions for Components A, B, and C:

- Does the research evaluate an intervention for which evidence of effectiveness in the population of focus is lacking?
- Does the research go beyond measures of effectiveness to address theories of causation and challenges of implementation and adaptation for well-defined racial or ethnic minority populations under specific community contexts?

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?

Additional questions for Component A:

- Does the proposed project focus on multiple factors in the built environment and/or social connectedness that could result in measurable changes in exposures to carcinogens or cancer-related health behaviors within the study period?
- Does the proposed community-based intervention address systemic racism for one or more well-defined racial and ethnic groups?
- Does the intervention include multiple age groups, including adults?
- Is the theoretical basis for the proposed intervention well-justified?
- Does the approach include plans to examine intervention impact, challenges in implementation, and causal mechanisms of intervention effectiveness?
- Does the applicant provide power calculations demonstrating proposed sample size is sufficient to detect effects in measures of carcinogen exposure or measures of cancer-related behaviors within the project period?
- Does the applicant provide a detailed timeline with realistic and measurable milestones for proposed project activities?

Additional questions for Component B:

- Does the proposed project focus on community-clinical linkages and/or the built environment that could improve the use of or follow-up for one or more cancer screening tests within the study period?
- Does the proposed community-based intervention address systemic racism for one or more well-defined racial and ethnic groups?
- Does the intervention focus only cancer screening tests with A or B recommendations from the U.S. Preventive Services Task Force?
- Does the population of focus include persons within the recommended age ranges for the selected screening tests?
- Is the theoretical basis for the proposed intervention well-justified?
- Does the approach include plans to examine intervention impact, challenges in implementation, and causal mechanisms of intervention effectiveness?
- Does the applicant provide power calculations demonstrating proposed sample size is sufficient to detect effects in key screening outcomes within the project period?
- Does the applicant provide a detailed timeline with realistic and measurable milestones for proposed project activities?

Additional questions for Component C:

- Does the proposed project focus on multiple factors in the built environment and/or social connectedness and/or community clinical linkages that could improve the health and well-being of cancer survivors within the study period?
- Does the proposed community-based intervention address systemic racism for one or more well-defined racial and ethnic groups?
- Does the population of focus include persons within the age range of 45-84 years?

- Is the theoretical basis for the proposed intervention well-justified?
- Does the approach include plans to examine intervention impact, challenges in implementation, and causal mechanisms of intervention effectiveness?
- Does the applicant provide power calculations demonstrating proposed sample size is sufficient to detect effects in key intervention outcomes within the project period?
- Does the applicant provide a detailed timeline with realistic and measurable milestones for proposed project activities?

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?

Additional questions for Components A, B, and C:

- Does the project utilize critical partnerships or collaborations?
- Does the project support key partner involvement throughout the research process?
- Does the application provide letters of commitment from key partner organizations?

2. Additional Review Criteria

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

Protections for Human Subjects

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

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

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

Inclusion of Women, Minorities, and Children

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

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

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.

Data Management Plan

CDC requires awardees for projects that involve the collection or generation of public health data with federal funds to submit a Data Management Plan (DMP) prior to the initiation of generating or collecting public health data unless CDC will aggregate and disseminate the data. *Public health data* means digitally recorded factual material commonly accepted in the

scientific community as a basis for public health findings, conclusions, and implementation. In initial funding applications, the DMP should be addressed within the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application, either as a stand-alone DMP within this section or with a statement explaining why a DMP is not included. The DMP must be updated and submitted to CDC at least annually, or whenever plans for data collection or generation activities change. Costs associated with developing and implementing a DMP, including costs of sharing, archiving and long-term preservation, may be included in the budget submissions for grants and cooperative agreements. The contents of the DMP are described in AR-25. Visit link https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm for DMP Template and Guidance.

Public health data are expected to be made freely available to the public (in a de-identified format) and archived long-term unless there are compelling reasons not to do so. When it is not feasible to make data freely available to the public, it may be possible to make data available to users on a restricted basis. The DMP should describe the expected level of public access, if any, and must justify the planned access level and describe how privacy and confidentiality will be protected. The final version of a collected and/or generated data set intended for release or sharing should be made available within thirty (30) months after the end of the data collection or generation, except surveillance data from ongoing surveillance systems which should be made accessible within 12 months of the end of a collection cycle. Awardees who fail to release public health data in a timely fashion may be subject to procedures normally used to address lack of compliance consistent with applicable authorities, regulations, policies or terms of their award. For data underlying scientific publications such as peer review journal articles, awardee should make the data available coincident with publication of the paper, unless the data set is already available via a release or sharing mechanism. At a minimum, release of the data set accompanying a scientific paper should consist of a machine-readable version of the data tables shown in the paper.

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

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

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

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

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

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

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

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 only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.

- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding recommendations:

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

    - Evaluation of interventions that address policy, environment, or system changes in social determinants of health (the bottom tiers of the health impact pyramid in Section 1.1 Background and Purpose).
    - For Component A, interventions that address the built environment and/or social connectedness; for Component B, interventions that address the built environment and/or community-clinical linkages; and for Component C, interventions that address the built environment and/or community-clinical linkages and/or social connectedness.

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: https://www.archives.gov/federal-register/cfr.

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements

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

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

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

AR-29: Compliance with EO13513, Federal Leadership on Reducing Text Messaging while

Driving, October 1, 2009

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

AR-31: Distinguishing Public Health Research and Public Health Nonresearch

AR-32: FY 2015 Enacted General Provisions

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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/additional-requirements/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/additional-requirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

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

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Nonresearch Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html.
- Obtaining and maintaining the appropriate Institutional Review Board approvals for all

institutions or individuals participating in research involving human subjects
- Maintaining an adequate management and staffing plan to support all project activities.
- Recruiting technical and content experts with proper skills and experience for all aspects of the expanded intervention.
- Establishing and maintaining communication with key research and community partners.
- Forming and convening a community advisory board consisting of representatives of partnering organizations, key stakeholders, government agencies, nonprofit organizations, and community residents.
- 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 has 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 https://www.cdc.gov/grants/additionalrequirements/ar-25.html.
- Participating in meetings of the community advisory board in an advisory capacity.
- Contributing scientific expertise and consultation at all stages of the project.
- Facilitating communications with other CDC staff and CDC-funded partners to share relevant knowledge and experience.
- Participating in the presentation of results and may be co-authors on publications and conference presentations.
- Facilitating the dissemination and translation of findings for use in cancer prevention and control programs.

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.

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.

Areas of Joint Responsibility include:

- None; 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 the Payment Management System (PMS) **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 to be submitted **120 days after the end of the period of performance**.

B. Content of Reports

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

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

a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
b) Leadership/Partnership: list project collaborations and describe the role of external partners.

- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. Questions to consider in preparing this section include:

- How will the scientific findings be translated into public health practice or inform public health policy?

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

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

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

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

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

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

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

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project’s data collection such as changes to initial data collection plan,

challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through the Payment Management System (PMS) within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.
Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.
The due date for final FFRs is 120 days after the Period of Performance end date.
Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).
FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.
Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https://era.nih.gov/ 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, health care 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

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

Application Submission Contact

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.govHours: Monday - Friday, 7am - 8pm U.S. Eastern Time

Scientific/Research Contacts

Sue Shaw, MPH
Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
Atlanta, GA 30341
Telephone: 770.488.6142
Email: zgx7@cdc.gov

Peer Review Contact

Jaya Raman, Ph.D.
Scientific Review Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
Atlanta, GA 30341
Telephone: 770.488.6511
Email: kva@cdc.gov

Financial/Grants Management Contact(s)

Dwayne R. Cooper, Sr.
Grants Management Specialist
Office of Financial Resources (OFR)
Office of Grant Services
Telephone: 770.488.2874
Email: DCooper1@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.

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

Interventions, evaluations, and/or research and reports in this NOFO are for the critical public health purpose of reducing cancer disparities and improving population health and are aimed at populations experiencing such disparities though are not limited.

Section VIII. Other Information
Appendix A. Questions from Potential Applicants and CDC Responses

1. The 3 publications that are "not publicly available" do NOT count towards the 10 PDFs or the 35 pages?
   1a. Is each of the 10 PDFs allowed up to 35 pages or is this a total for all 10 PDFs?

   Response: 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. This 35-page limit includes the 3 publications that are not publicly available. Below are the NOFO sections that address page limits.

   - Section IV.6. Appendix - Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publicly available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

   - Section IV.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. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

2. Kindly confirm if a Non-us organisation can submit an application for this opportunity number: RFA-DP-21-003. The NOFO document lists eligibility criteria that specifically don't mention non-us entities, however considering the importance of Cancer, I thought to ask...

   Response: Foreign organizations are not eligible to apply for DP21-003. This information is in the NOFO, Section III.2 Foreign Organizations, which includes the below information.

   - Foreign Organizations are not eligible to apply.
   - Foreign components of U.S. Organizations are not eligible to apply.
   - For this announcement, applicants may not include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Cancer Screening - Although this RFA is clearly about evaluation of existing interventions, can some of our effort be expended on expanding the intervention itself? This question arises because there is language in the RFA about the on-going intervention "expanding as needed to generate evidence…" (page 9). And "Multi-sector and multilevel interventions are encouraged" (also page 9). Finally " Expand the intervention population, as needed, to achieve a sufficiently large number of persons…" (page 12).

   Can you please clarify then if we are allowed to expand our intervention in ways that increase sample size and data collection to facilitate evaluation or are we to evaluate the existing intervention as is?

   Response: The intervention may be expanded, as needed, to increase sample size to allow findings to be generated. Below are the locations in the NOFO that address this question.

   1. In the NOFO Section I.2 Approach, is the following information regarding expanding the intervention.
      - Applicants should propose rigorous evaluation research of an on-going intervention, expanded as needed, to generate evidence about cancer prevention and control strategies that involve structural/systemic changes in social determinants of health (see lower tiers of the impact

pyramid in Section1.1 Background and Purpose), including systemic racism. Expand the intervention population, as needed, to achieve a sufficiently large number of persons within one or more racial or ethnic minority groups to allow findings to be generated for that group. A power analysis should be used to demonstrate that the proposed sample size is adequate to detect an intervention effect within the study period.

- Expand the intervention population, as needed, to achieve a sufficiently large number of persons within one or more racial or ethnic minority groups to allow findings to be generated for that group. A power analysis should be used to demonstrate that the proposed sample size is adequate to detect an intervention effect within the study period.

2. In Section IV. Research Plan is application content information.
   - Describe the history of the on-going community intervention, the entity implementing the intervention, its original aims and scope, and how the intervention will be expanded for this evaluation research project.

4. I am interested in applying for the above project, Component C. The word 'cancer' is broad. Would it be acceptable to focus on one particular type of cancer in one area for development ? E.g breast cancer.

   Response: Yes. This information is in the NOFO, Part 1.2. Approach, Component C: Health and Wellbeing of Cancer Survivors is information about the target population for this Component, which is provided below.

   Target Population - The intervention population should be adults with a personal history of adult-onset cancer of any type (other than non-melanoma skin cancer) who have completed initial course of treatment with the intent to cure but may be continuing long-term hormonal treatment. Most of the intervention population should fall within the age range of 45-84 years.

5. Although this RFA is clearly about evaluation of existing interventions, can some of our effort be expended on expanding the intervention itself? This question arises because there is language in the RFA about the on-going intervention "expanding as needed to generate evidence…" (page 9). And "Multi-sector and multilevel interventions are encouraged" (also page 9). Finally " Expand the intervention population, as needed, to achieve a sufficiently large number of persons…" (page 12).
   Can you please clarify then if we are allowed to expand our intervention in ways that increase sample size and data collection to facilitate evaluation or are we to evaluate the existing intervention as is?

   Response: In the NOFO, Part 1.2 Approach, it states the following, which applies to all Components.

   Applicants should propose rigorous evaluation research of an on-going intervention, expanded as needed, to generate evidence about cancer prevention and control strategies that involve structural/systemic changes in social determinants of health (see lower tiers of the impact pyramid in Section1.1 Background and Purpose), including systemic racism.

   Also, in the Approach, under Recipient is Expected to: it states, Expand the intervention population, as needed, to achieve a sufficiently large number of persons within a well-defined racial or ethnic minority group to allow findings to be generated for that group and yield stable estimates of intervention effects. A power analysis should be used to demonstrate that the proposed sample size is adequate to detect an intervention effect within the study period.

6. Are the Letters of Commitment from partner organization required in the Research Strategy section and counted as part of the 25-page limit or are the letters part of the ancillary documents?

a. Is the detailed budget and the line item justification noted in the research strategy section of the FOA required in the research strategy section or is it required in the budget section of the NIH ASSIST application?
b. Are the below requirements (standard NIH/AHRQ requirements) required as part of the FOA?

Response: CDC uses the SF424 R&R Application Guide for applicants to prepare and submit research applications. The below information is specific to this NOFO. For additional information on the application please refer to the SF424 R&R.

- Section IV.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. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

- Section IV.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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general-forms-f.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.

- Section IV.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-f/general-forms-f.pdf and http://grants.nih.gov/grants/how-to-apply-application-guide.htm 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-f/general-forms-f.pdf and here: http://grants.nih.gov/grants/how-to-apply-application-guide.htm must be followed along with any additional instructions provided in the NOFO.

7. Component C - Does the cancer survivor group definition exclude stages 0 and 4? In the NOFO it mentioned completion of intent to cure treatment, which seems to exclude stage 4. We also know that stage 0 patients (e.g. DCIS) go through treatment, but that they are not reported as cancer cases.

   Response: In the NOFO, Section 1. Approach is information about the Target Population, as follows.

   Component C: Cancer Survivors - The intervention should be designed to address the needs of people from one or more racial or ethnic minority groups who experience disparities in health outcomes after a cancer diagnosis. The intervention population should be adults with a personal history of adult-onset cancer of any type (other than non-melanoma skin cancer) **who have completed initial course of treatment** with the intent to cure **but may be continuing long-term** hormonal treatment. Most of the intervention population should fall within the age range of 45-84 years.

8. Within the 25-page limit are we supposed to include the study team management, timeline, etc., separately from PHS documents? Since we are proposing a behavioral trial, it seems like some of these documents are also included there. Can you confirm that they should be in both places?

   Response: In the NOFO, Part 1. Overview Information, is states, Note: The Research Strategy component of the Research Plan is limited to 25 pages.

   Also, in the NOFO, Section IV.7. Page Limitations is the following information.

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

9. My grants administrator noted that the application in ASSIST looks like a typical NIH format without any special considerations for the documents requested for this proposal. In the NOFO the instructions seem to suggest SF424 guidelines- should the NOFO guidelines supersede these?

   Response: In the NOFO, Section IV.2. Content and Form of Application Submission, it states, 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-f/general-forms-f.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.

10. Component B: Cancer Screening - Can funding through this opportunity support an intervention itself or strictly the evaluation research? If we applied, we would want the funding to support the cancer screening intervention itself (staff costs, patients costs, etc.) as well as costs directly related to the evaluation (staff costs, external partnership, etc.).

    Response: In the NOFO Part I.2 Approach, is the purpose of Component B: Cancer Screening and information about the costs associated with the provision of medical services.

    - The purpose of Component B: Cancer Screening is to conduct evaluation research on an innovative, multi-sector intervention to reduce inequities in the receipt of appropriate screening and follow-up services for breast, cervical, colorectal or lung cancer (on-time initial screening, routine re-screening at recommended intervals, and appropriate follow-up after inconclusive/incomplete screening and abnormal test results) among one or more racial or ethnic populations who experience disparities in cancer screenings. This research will generate knowledge about the implementation, impact, and causal mechanisms of the intervention's effect on the cancer screening outcomes. Research in this component will also build the evidence base for community-based, structural interventions on social determinants to decrease racial and ethnic disparities in the receipt of recommended cancer screening services

    Recipient is expected to:
    Select a promising, on-going community-based intervention to improve the use of, and follow up for, one or more cancer screening tests as recommended in one or more racial or ethnic minority groups. The intervention should focus on one or more cancer screening tests with A or B recommendations from the U.S. Preventive Services Task Force: breast [43], colorectal [44], cervical [45], or lung cancer [46] and involve community-clinical linkages, and/or the built environment. An intervention that does not have cancer screening as its primary purpose may be studied, but the intervention should address one or more known barriers to cancer screening and be reasonably expected to improve cancer screening outcomes. Costs associated with the provision of medical services are not supported by this NOFO.

11. Are indirects allowed without a negotiated rate?

Response: Without an indirect cost rate agreement (ICRA), if the organization is new and never had an ICRA, the organization can choose a de minimus rate of 10%. If the organization is an institution of higher education (IHE), or a hospital, the organization can continue to use any existing rate through an existing ICRA, but otherwise they would not be able to use indirect costs without a negotiated rate.

This information is provided in **45 CFR Part 75, Subpart E, Direct and Indirect Costs**, and **45 CFR 75.414(f)**.

12. Because prostate cancer was not mentioned anywhere in your document, would A - Primary prostate cancer prevention and C – Health and wellbeing of Prostate Cancer Survivors be considered as a valid submission?

Response:

A. **Component A: Primary Cancer Prevention** does not prohibit an applicant addressing prostate cancer. In the NOFO, Part I.2 Approach, Component A: Primary Cancer Prevention, the NOFO provides information on the what the intervention may not include under the following recipient expectation.

Recipient is expected to:
1. Select a promising, on-going intervention being implemented in a community that focuses on the built environment and/or social connectedness to reduce cancer risk among people from one or more racial or ethnic minority groups. The intervention should be informed by evidence that suggests the proposed approach, which could involve influencing policies, programs or social norms, could result in change in exposures to carcinogens or cancer-related health behaviors within the study period. The original purpose of the intervention need not be cancer prevention, provided the intended outcomes include reduced carcinogenic exposures or changes in behaviors that lead to reduced cancer risk. Interventions that address multiple or clusters of cancer risk factors (exposures and/or health behaviors) are encouraged. The intervention should not include: 1) chemo-preventive agents, drugs, or nutritional supplements of any kind; 2) vaccines; 3) prophylactic surgery; or 4) screening tests for cancer or pre-cancer conditions.

B. **Component C: Health and Wellbeing of Cancer Survivors** does not prohibit an applicant addressing prostate cancer. In the NOFO Part I.2 Approach, Component C: Health and Wellbeing of Cancer Survivors provides information on the outcomes of interest for this component, under the following recipient expectation.

Recipient is expected to:
1. Select a promising, on-going community-based intervention focused on community-clinical linkages and/or the built environment and/or social connectedness to address one or more known barriers to health and wellbeing among survivors of adult cancers from one or more racial or ethnic minority groups. Costs associated with the provision of medical services are not supported by this NOFO. The intervention outcomes of interest should include one or more of the following:
o reduced barriers to healthy behaviors;
o improved access to recommended preventive health services and behavioral counseling;
o reduced financial toxicity from recurring medical care costs;
o improved management, reduction or elimination of co-occurring chronic conditions such as diabetes and obesity;
o reduced barriers to returning to/remaining at work;

o improved quality of mental and physical health-related quality of life.

13. I am writing to confirm our understanding of the budget allowances for applications to CDC RFA-DP-21-003. Based on the RFA information it appears that each application focuses on one component and has allowable costs of $1,000,000/year **inclusive** of both direct and indirect costs. Can you confirm that this is the appropriate reading of the RFA?

    Response: Applicants may apply for one Component. The estimated $1,000,000 funding per year includes both direct and indirect. This information is in the following sections in the NOFO.

    Part 1. Executive Summary

    - Number of Applications - Only one application per institution (normally identified by having a unique DUNS number) is allowed. Applicants may apply for one (1) Component of funding (Component A, or Component B, or Component C).

    - Funds Available and Anticipated Number of Awards - The estimated total funding (direct and indirect) for the five-year period of performance, September 30, 2021 to September 29, 2026, is $15,000,000 to fund three (3) awards, one in each of the three Components.

    - Budget and Period of Performance - The estimated total funding for the first budget period, 9/30/2021-9/29/2022, is $3,000,000 (direct and indirect). The estimated total funding for the entire period of performance, 9/30/2021-9/29/2026, is $15,000,000 (direct and indirect).

    Component A: Primary Cancer Prevention
    Period of Performance: 5 years (09/30/2021 to 09/29/2026)
    Estimated Funding Per Year: Up to $1,000,000

    Component B: Cancer Screening
    Period of Performance: 5 years (09/30/2021 to 09/29/2026)
    Estimated Funding Per Year: Up to $1,000,000

    Component C: Health and Wellbeing of Cancer Survivors
    Period of Performance: 5 years (09/30/2021 to 09/29/2026)
    Estimated Funding Per Year: Up to $1,000,000

    Section II. Award Information

    - Estimated Funding - The estimated total funding (direct and indirect) for the five-year period of performance, September 30, 2021 to September 29, 2026 is $15,000,000 to fund three (3) awards in three Components.

    Component A: Primary Cancer Prevention
    Number of Awards: 1
    Estimated Funding: $5,000,000

    Component B: Cancer Screening
    Number of Awards: 1
    Estimated Funding: $5,000,000

    Component C: Health and Wellbeing of Cancer Survivors
    Number of Awards: 1
    Estimated Funding: $5,000,000

14. I understand that only one application per institution is allowed in response to this RFA. Can you advise if an investigator is allowed to participate as key personnel in multiple applications, and if my institution is allowed to collaborate on another institution's application as a subcontractor, if my institution is planning to submit our own application?

    Response: The NOFO does not prohibit investigators serving as key personnel in multiple applications or for applicants to collaborate on another institution's application as a subcontractor.

15. Is the research intended to solely focus on racial and ethnic minority groups, or can it include underserved populations more generally, as long as racial and ethnic minorities are included?

    Response: In the NOFO, Section 1.2 Target Population, it says "Component C: Cancer Survivors - The intervention should be designed to address the needs of people from one or more racial or ethnic minority groups who experience disparities in health outcomes after a cancer diagnosis. The intervention population should be adults with a personal history of adult-onset cancer of any type (other than non-melanoma skin cancer) who have completed initial course of treatment with the intent to cure but may be continuing long-term hormonal treatment. Most of the intervention population should fall within the age range of 45-84 years."

    In the NOFO, Section 2, Approach, it says: "The research is expected to go beyond measures of effectiveness to address theories of causation and issues of implementation and adaptation for well-defined racial or ethnic minority populations under specific community contexts."

    Also in the NOFO, in Section V. Application Review Information, is review criteria related to this question. For Component C: Cancer Survivors, the following question is included under Approach - "Does the proposed community-based intervention address systemic racism for one or more well-defined racial and ethnic groups?"

16. Is the study to be powered (p. 14) to demonstrate that the proposed sample size is adequate to detect an intervention effect for the minority groups specifically? Adequate power will be very hard to achieve for racial/ethnic minority cancer survivors who are treated with intent to cure (i.e., local or regional stage disease) due to relatively low numbers of minority patients meeting criteria

    Response: In the NOFO, Section 1.2 Approach, under Outcomes/Objective, for Component C: Cancer Survivors, it provides the below requirement.
    "Expand the intervention population, as needed, to generate evidence about the effectiveness of this intervention and generate stable estimates of outcome measures for cancer survivors from one or more racial or ethnic minority groups. A power analysis should be used to demonstrate that the proposed sample size is adequate to detect an intervention effect within the study period."

    Also in the NOFO, Section IV. Research Plan, Component C: Cancer Survivors, applicants are asked to include the below information in the application.
    "Describe and provide power analyses conducted to determine the appropriate sample size for evaluating the intervention in the population of focus. The study should be powered to detect change in key intervention outcomes."

17. Could CDC provide an example of an evidence-based theoretical framework that addresses systemic racism as it applies to cancer survivors?

    Response: In the NOFO, Section 1.2 Approach, Under Outcomes/Objectives, for Component C: Cancer Survivors, it provides the requirement that the proposed research use an evidence-based

theoretical framework to address systemic racism. Each applicant will need to determine the appropriate evidence-based theoretical framework for their proposed research.

18. Can a component of the intervention occur near the time of diagnosis, with follow-up starting after treatment is completed? We are considering a financial toxicity intervention for our application. The effect of this intervention will be greatest if we identify high risk populations near the time diagnosis

    Response: In the NOFO, Section 1.2 Target Population, it says "Component C: Cancer Survivors - The intervention should be designed to address the needs of people from one or more racial or ethnic minority groups who experience disparities in health outcomes after a cancer diagnosis. The intervention population should be adults with a personal history of adult-onset cancer of any type (other than non-melanoma skin cancer) who have completed initial course of treatment with the intent to cure but may be continuing long-term hormonal treatment. Most of the intervention population should fall within the age range of 45-84 years.

19. Should the focus be on an existing intervention or is it acceptable to propose a novel intervention? There are few existing interventions to address financial toxicity. We believe there are opportunities to test novel approaches.

    Response: The intervention should be an existing, on-going intervention within the community with a well-defined racial or ethnic minority population under specific community contexts. This information is in the NOFO Section 2.2 Approach.
    Section 2.2 Approach - Applicants should propose rigorous evaluation research of an on-going intervention, expanded as needed, to generate evidence about cancer prevention and control strategies that involve structural/systemic changes in social determinants of health (see lower tiers of the impact pyramid in Section 1.1 Background and Purpose), including systemic racism. The research is expected to go beyond measures of effectiveness to address theories of causation and issues of implementation and adaptation for well-defined racial or ethnic minority populations under specific community contexts

20. Component C – To what degree does the intervention have to already exist in the form and for the population being evaluated? We have delivered digital health support, community health workers/ peer navigation, implicit bias training, and patient navigation--all components we are considering for our proposal--but not as a coordinated effort within with an ability to target and then scale in specific populations. Is this okay? Is the RFA is seeking evaluation within certain cancer types, survivor ages, stages, etc.

    Response:
    A. The intervention should be an existing, on-going intervention within the community with a well-defined racial or ethnic minority population under specific community contexts. This information is in the NOFO Section 2.2 Approach.
    Section 2.2 Approach - Applicants should propose rigorous evaluation research of an on-going intervention, expanded as needed, to generate evidence about cancer prevention and control strategies that involve structural/systemic changes in social determinants of health (see lower tiers of the impact pyramid in Section 1.1 Background and Purpose), including systemic racism. The research is expected to go beyond measures of effectiveness to address theories of causation and issues of implementation and adaptation for well-defined racial or ethnic minority populations under specific community contexts.

    B. Section 1.1 Public Health Impact and Section 2.2 Objectives/Outcomes and Translation Plan provide information about scaling of the intervention.

Section 1.1 Public Health Impact - This research will fill important gaps in knowledge about:
1) the implementation and potential for scaling of innovative interventions to reduce racial and ethnic disparities in cancer outcomes;
2) the resources required for implementation and scaling;
3) the impact of novel community-based approaches to reduce health inequities and improve cancer-related outcomes in economically or socially disadvantaged populations. In addition, the evaluation research will contribute to an underlying theory of causation or reveal specific elements and strategies that contribute to intervention effectiveness.

Section 2.2 Objectives/Outcomes, Component C: Health and Wellbeing of Cancer Survivors, Objective 4. Determine challenges in implementation and adaptation for one or more racial and ethnic minority groups in a specific setting, and make recommendations for challenges to be addressed when repeating or scaling the intervention.

Recipient is expected to:

- Prepare a final report that includes recommendations for translation, adaptation, scaling and sustaining the intervention focused on one or more racial or ethnic minority groups under specific community contexts.
- Develop multiple manuscripts for publication in the scientific literature that present project findings and provide insights for adaptation and scaling.

Section 2.2 Translation Plan - One or more reports of findings and recommendations for implementing, translating, adapting or scaling the intervention are expected to be submitted to peer-reviewed journals and disseminated through diverse media such as a study website, guidelines, toolkits, and policy briefs

C. In the NOFO, Section 2.2 Target Population is the following information -The intervention population should be adults with a personal history of adult-onset cancer of any type (other than non-melanoma skin cancer) who have completed initial course of treatment with the intent to cure but may be continuing long-term hormonal treatment. Most of the intervention population should fall within the age range of 45-84 years.

D. In the NOFO Section 2.2 Objectives/Outcomes, under Recipient is Expected, is information about the focus of this Component. The section provides the below information.
Select a promising, on-going community-based intervention focused on community-clinical linkages and/or the built environment and/or social connectedness to address one or more known barriers to health and wellbeing among survivors of adult cancers from one or more racial or ethnic minority groups. The intervention outcomes of interest for Component C should include one or more of the following:

- reduced barriers to healthy behaviors;
- improved access to recommended preventive health services and behavioral counseling;
- reduced financial toxicity from recurring medical care costs;
- improved management, reduction or elimination of co-occurring chronic conditions such as diabetes and obesity;
- reduced barriers to returning to/remaining at work;
- improved quality of mental and physical health-related quality of life.

21. The funding announcement mentions that a letter of intent is due on Jan 11, 2021. Who is responsible for receiving the letter of intent for this grant? What is their contact information?

Response: In the NOFO, Section IV.3 Letter of Intent, the NOFO states that the letter of intent should be emailed to Sue Shaw at zgx7@cdc.gov.

22. Our organization is vetting the CDC RFP #: RFA-DP-21-003 (Reducing Inequities in Cancer Outcomes through Community-Based Interventions on SDOH) and we have a clarifying question. Our initial concept is to research the impact on cancer disparities by placing social workers who will screen for social determinants of health at our cancer center. Our team is interpreting differently if this grant would fund the actual implementation of the intervention (in this case social workers, social determinant screening, etc.) in addition to the research.

    Since the RFP mentions the expansion of interventions and that evaluation research includes the implementation of intervention, it sounded like intervention implementation costs would be covered. Intervention costs also aren't listed in the ineligible expense section. However, we wanted to confirm with you: ***is this grant aimed solely at only funding research/evaluation activities?***

    Response: This NOFO is intended to fund only evaluation research, as described in this NOFO.

    In the NOFO Section 1.1. Background and Purpose, it states the purpose of this NOFO is to conduct evaluation research to build an evidence base of innovative, community-based, structural interventions across multiple social determinants of health to reduce racial and ethnic disparities in cancer outcomes.

    For this NOFO, evaluation research is defined as the systematic application of public health research procedures for assessing the conceptualization, design, implementation, effectiveness and utility of public health interventions.

    The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) seeks to achieve health equity through multisectoral and multilevel collaboration on the social determinants of health. This research NOFO will support NCCDPHP work in these priority areas:

    - **Built environment**: human-made surroundings where people live, learn, work, play, worship and age that influence overall community health and individual behaviors that drive health. A healthy built environment facilitates access to transportation and physical resources that enhance quality of life, minimizes exposure to environmental contaminants, and supports physical activity, safe recreation, a safe workplace, and other protective factors.
    - **Community-clinical linkages**: connections made among health care systems and services, public health agencies, and community-based organizations to improve population health. Effective community-clinical linkages improve cancer outcomes by increasing access to and utilization of preventive and chronic care services in local communities.
    - **Social connectedness**: the degree to which individuals or groups of individuals have a desired number, quality, and diversity of relationships that create a sense of belonging and being cared for, valued, and supported. A high degree of social connectedness can increase the likelihood of individuals engaging in positive health behaviors, ultimately improving health outcomes by moderating the negative health effects of adversities such as stress, trauma, adversity, anxiety, and depression. Social connectedness can create opportunities to access resources that might otherwise be unavailable. In addition, social connectedness can contribute to collective efficacy to change policy, programs, and social norms.

    Also in the NOFO, Section 1.2 Approach, it states Applicants should propose rigorous evaluation research of an on-going intervention, expanded as needed, to generate evidence about cancer prevention and control strategies that involve structural/systemic changes in social determinants of health (see lower tiers of the impact pyramid in Section 1.1 Background and Purpose), including systemic racism. The research is expected to go beyond measures of effectiveness to address theories of causation and issues of implementation and adaptation for well-defined racial or ethnic minority populations under specific community contexts.