

Centers for Disease Control and Prevention

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

Connecting Organizations and People to Empower Diabetes Prevention and Treatment (Connections)

RFA-DP-25-041

01/06/2025

Table of Contents

Section I. Funding Opportunity Description 4
Section II. Award Information....17
Section III. Eligibility Information 18
Section IV. Application and Submission Information....22
Section V. Application Review Information 33
Section VI. Award Administration Information 40
Section VII. Agency Contacts 52
Section VIII. Other Information 53

Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

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

Notice of Funding Opportunity (NOFO) Title

Connecting Organizations and People to Empower Diabetes Prevention and Treatment (Connections)

Activity Code

U18 - Research Demonstration Cooperative Agreements

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-25-041

Assistance Listings Number(s)

93.945

Category of Funding Activity

HL - Health

NOFO Purpose

The purpose of this NOFO is to support evaluation of the effectiveness of existing Community-Clinical Linkage or Social Connectedness programs to reduce disparities in diabetes risk factors, incidence, or complications. Additionally, research supported by this NOFO will assess how various mechanisms (e.g., improving specific social or environmental conditions, mental health,

or self-efficacy) will impact diabetes outcomes. Specifically, the results of this funded research NOFO will: (a) guide future scaling regarding programs using Community-Clinical Linkage and Social Connectedness; (b) demonstrate mitigation of observed disparities in diabetes risk factors, incidence, and complications through Community-Clinical Linkage and Social Connectedness programs; and (c) inform the understanding of the mechanisms by which Community-Clinical Linkage and Social Connectedness programs achieve successful health outcomes and the features that characterize effective programs.

Key Dates

Publication Date:
To receive notification of any changes to RFA-DP-25-041, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date:
12/02/2024

Application Due Date:
01/06/2025

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 11:59 PM U.S. Eastern Time.

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

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

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

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

Scientific Merit Review:
03/11/2025
This date is an estimate.

Secondary Review:
04/28/2025

This date is an estimate.

Estimated Start Date:
09/30/2025

Expiration Date:
01/07/2025

Required Application Instructions

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

Note: The Research Strategy component of the Research Plan is limited to 12 pages.

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

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

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

Executive Summary

- **Purpose**: The purpose of this NOFO is to support evaluation of the effectiveness of existing Community-Clinical Linkage or Social Connectedness programs to reduce disparities in diabetes risk factors, incidence, or complications. Additionally, research supported by this NOFO will assess how various mechanisms (e.g., improving specific social or environmental conditions, mental health, or self-efficacy) will impact diabetes outcomes. Specifically, the results of this funded research NOFO will: (a) guide future scaling regarding programs using Community-Clinical Linkage and Social Connectedness; (b) demonstrate mitigation of observed disparities in diabetes risk factors, incidence, and complications through Community-Clinical Linkage and Social Connectedness programs; and (c) inform the understanding of the mechanisms by which Community-Clinical Linkage and Social Connectedness programs achieve successful health outcomes and the features that characterize effective programs.
- **Mechanism of Support**: U18
- **Funds Available and Anticipated Number of Awards**: The estimated total funding available, including direct and indirect costs, for the entire three (3)-year period of performance is **$3,150,000.00.** The number of awards will be **three (3).** Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded, and the number of awards will depend upon the number, quality, duration and cost of the applications received.

- **Budget and Period of Performance**: The estimated total funding (direct and indirect) for the first year (12-month budget period) will be **$1,050,000** with individual awards of approximately **$350,000** each for three awards. The estimated total funding (direct and indirect) for the entire Period of Performance will be **$3,150,000.00**. The period of performance is anticipated to run from **09/30/2025 to 09/29/2028.**
- **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 of this announcement are eligible to apply.
- **Eligible Project Directors/Principals 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. CDC does not make awards to individuals directly. Individuals from organizations that are uniquely prepared to examine research relevant to undeserved groups, including sexual orientation and gender identity minorities as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs**: There will only be one PD/PI for each application.
- **Number of Applications**: Only one application per institution (normally identified by having a unique UEI number) is allowed.
- **Application Type**: New
- **Application Materials**: See Section IV.1 for application materials. Please note that SF424 (R&R) Form H is to be used when completing the application package. Please see https://grants.nih.gov/grants/how-to-apply-application-guide.html

Section I. Funding Opportunity Description

Statutory Authority

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

1. Background and Purpose

Health Equity, Health Disparities and the Social Determinates of Health

Health equity is the state in which everyone has a fair and just opportunity to attain their highest level of health. Health Disparities are preventable differences in the burden of disease or opportunities to achieve optimal health that are experienced by populations that have been socially, economically, geographically, and environmentally disadvantaged.

Eliminating health disparities and advancing health equity are foundational to Health and Human Service's Healthy People 2030. Many health disparities stem from the unequal distribution of social and environmental factors, such as safe and stable housing, access to nutritious food, reliable transportation, employment and financial security, discrimination, education, and other stressors (1). These and other nonmedical factors which constitute the conditions in which people are born, grow, work, live, and age are referred to as the Social Determinants of Health (SDOH). The confluence of SDOH factors impacts health behaviors and physical and mental health (2), accounting for 50-60% of poor health outcomes (1). Breaking down barriers to health equity by

addressing SDOH is a top priority for CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP).

Health Disparities in Diabetes

Diabetes is the eighth leading cause of death in the United States (3) and is responsible for approximately 12% of deaths annually (4). People with diabetes also have significant clinical, physical, and psychological comorbidities including macro- and microvascular disease, foot and leg amputations, depression, and diabetes distress (5). Significant health disparities in diabetes incidence and rates of diabetes complications exist according to race and ethnicity and socioeconomic status (6). Achieving health equity in diabetes prevention and treatment requires overcoming economic, social, and other obstacles to health and health care to eliminate preventable health disparities. CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) supports this effort by addressing the SDOH that drive inequity in health outcomes. Two key approaches of NCCDPHP's effort to reduce health disparities by addressing SDOH are Community-Clinical Linkages and Social Connectedness. Evaluating how Community-Clinical Linkages and Social Connectedness programs may reduce disparities in diabetes risk factors, incidence, and complications is the primary focus of this NOFO.

Community-Clinical Linkages as a Strategy to Address Diabetes Disparities

Community-Clinical Linkages are connections made among health care systems and services, public health agencies, and community-based organizations to improve population health. Effective Community-Clinical Linkages improve chronic disease outcomes by increasing access to and utilization of preventive and chronic care services in local communities (7). They represent a promising approach to addressing the social and environmental factors that may be driving disparities in diabetes related risk factors, incidence and complications. Broadly, Community-Clinical Linkage Programs may involve connecting people to community or clinical services through dedicated Community Health Workers or Health Navigators, connecting people to community or clinical services through referral systems, physically co-locating clinical or community resources together, or through a combination of these approaches:

- Integrating Community Health Workers (CHW), Health Navigators, Community Health Representatives, or Promotoras into clinical teams.
    - This approach entails utilizing these dedicated staff members, who are often trusted members of the local community, to help to coordinate patient care and connect patients with non-medical social resources to improve disease management/health outcomes, increase access to community resources, and address health-related social needs. Research suggests that CHW programs can be effective at improving cardiovascular disease risk factors (8), access to care among rural populations (9), glycemic control among adults with diabetes (10-12), and reducing chronic disease related emergency department visits and hospitalizations (13).

- Establishing coordinated care/referral systems or patterns between clinical services and community resources, community partners, or the community sector.
    - This approach entails establishing relationships and referral systems between healthcare service providers and community organizations that assist in meeting patients' social needs such as housing, nutrition, transportation, and education.

These programs may include bi-directional systems where providers submit referrals to community organizations and the organization sends information to the provider. For example, health systems may connect patients with diabetes to community-based organizations providing diabetes self-management and education services (14) or they may refer patients at risk of diabetes with food insecurity to community food pantries or assist patients in applying for federal food security benefits (15).

- Physically co-locating and integrating community and clinical services (e.g., primary care services and social services) to create a continuum of care and reduce barriers to care and social need resources.
    - Some examples of this approach include integrating diabetes management resources within community pharmacies, locating social service assistance offices or food pantries in healthcare facilities, or using mobile health clinics to deliver services to populations with inadequate healthcare access. Community-Clinical Linkage pharmacy intervention studies have demonstrated improvements in body mass index (16, 17), hemoglobin A1c, total cholesterol, and blood pressure (18), and medication refill adherence (19). Mobile health clinics have demonstrated improvements in hypertension, blood lipid, and glycemic control (20).

Despite evidence suggesting Community-Clinical Linkage programs can be effective at improving diabetes and chronic disease outcomes, research gaps exist (21). For example, there is a need for information regarding the pathways, processes, and characteristics that make Community-Clinical Linkage interventions effective. More evidence is also needed on how Community-Clinical Linkage programs impact long term health outcomes, and how programs can be scaled cost-effectively for large scale implementation. There is also a need for further evidence on implementation with specific populations experiencing disparities in diabetes risk and complications, such as rural populations. Finally, there is a need to investigate how innovative technologies can be applied in Community-Clinical Linkage programs and to determine the effectiveness of providing services in innovative community settings such as barber shops and beauty salons.

Social Connectedness as a Strategy to Address Diabetes Disparities

Disparities in diabetes risk factors, incidence, and complications may also be driven, in part, by lack of opportunities for social connectedness(22). Social connectedness reflects the degree to which individuals and groups have the objective and subjective number, quality, and diversity of relationships to meet their functional social needs and includes a sense of belonging and being cared for, valued, and supported (23). Social relationships shape interpersonal interactions and intrapersonal experiences that can alter physiology across the life course. Hence, Social Connectedness, or lack thereof, is a significant determinant of mental, emotional, and physical health. Social isolation and loneliness are some of the indicators for lack of Social Connectedness. Social isolation is the objective state of having few social relationships or infrequent social contact with others, while loneliness is a subjective feeling of being isolated. Recent data from the Behavioral Risk Factor Surveillance System found that approximately 32% of adults report feeling lonely and approximately 25% of adults lack social and emotional support (24). Loneliness and lack of social and emotional support are more prevalent among

adults with lower incomes and less education, African American, Hispanic, and multiracial persons, and those who identify as gay, lesbian, bisexual, or transgender (25).

There are a variety of promising approaches to address Social Connectedness that may help reduce social isolation and loneliness. Previous studies have suggested that social isolation and loneliness are risk factors for diabetes incidence (26, 27) and complications among adults with diabetes (28) and that increased social support is associated with improved glycemic control and quality of life among adults with diabetes (1). Programs that enhance Social Connectedness can help reduce loneliness and social isolation and may improve self-efficacy and risk factors for diabetes incidence or complications (29, 30). Social Connectedness has also been shown to improve disease management and self-rated health of people with diabetes (31).

However, the overall evidence around Social Connectedness interventions shows mixed results and there remain important gaps in literature regarding Social Connectedness interventions (21, 32, 33) For example, more information is needed on the effectiveness of digital Social Connectedness interventions on various populations experiencing health disparities and the specific digital intervention activities and components that work best for each population. Evidence is also needed to compare the effectiveness of various intervention strategies and the delivery modes that are more effective for each. Also, more information is needed on the specific Social Connectedness intervention needs of people who live in settings or with conditions that put them at increased/higher risk of social isolation and loneliness such as those in rural communities, persons living with chronic diseases, and other populations disproportionately affected by social isolation and loneliness. Finally, research is needed on the effectiveness of culturally tailored interventions for specific populations. Thus, there remains the need to identify effective, culturally competent approaches and equitably adapt existing interventions to improve social connectedness among priority populations and assess how such interventions impact health seeking behaviors among these populations. For more information, see the World Health Organization evidence and gap map for in-person and digital interventions for reducing social isolation and loneliness in older adults.

Research Objectives of this NOFO

Community-Clinical Linkage or Social Connectedness programs show promising potential to improve diabetes risk factors and to reduce diabetes incidence and complications. However, further research is needed to address important gaps in the evidence base and determine how these programs can be used to address disparities in diabetes outcomes.

Therefore, the purpose of this NOFO is to support evaluation of the effectiveness of existing Community-Clinical Linkage or Social Connectedness programs to reduce disparities in diabetes risk factors, incidence, or complications. Additionally, research supported by this NOFO will assess how various mechanisms (e.g., improving specific social or environmental conditions, mental health, or self-efficacy) will impact diabetes outcomes. Specifically, the results of this funded research NOFO will: (a) guide future scaling regarding programs using Community-Clinical Linkage and Social Connectedness; (b) demonstrate mitigation of observed disparities in diabetes risk factors, incidence, and complications through Community-Clinical Linkage and Social Connectedness programs; and (c) inform the understanding of the mechanisms by which Community-Clinical Linkage and Social Connectedness programs achieve successful health outcomes and the features that characterize effective programs.

References

1. Hill-Briggs F, Adler NE, Berkowitz SA, Chin MH, Gary-Webb TL, Navas-Acien A, et al. Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. 2020;44(1):258-79. Epub 20201102. doi: 10.2337/dci20-0053. PubMed PMID: 33139407; PubMed Central PMCID: PMCPMC7783927.

2. Thimm-Kaiser M, Benzekri A, Guilamo-Ramos V. Conceptualizing the Mechanisms of Social Determinants of Health: A Heuristic Framework to Inform Future Directions for Mitigation. Milbank Q. 2023;101(2):486-526. Epub 20230416. doi: 10.1111/1468-0009.12642. PubMed PMID: 37062954; PubMed Central PMCID: PMCPMC10262397.

3. Centers for Disease Control and Prevention. Diabetes 2023 [cited 2024 March 30]. Available from: https://www.cdc.gov/nchs/fastats/diabetes.htm.

4. Stokes A, Preston SH. Deaths Attributable to Diabetes in the United States: Comparison of Data Sources and Estimation Approaches. PLoS One. 2017;12(1):e0170219. Epub 20170125. doi: 10.1371/journal.pone.0170219. PubMed PMID: 28121997; PubMed Central PMCID: PMCPMC5266275.

5. Centers for Disease Control and Prevention. Prevent Diabetes Complications 2022 [cited 2024 March 20]. Available from: Diabetes Complications | Diabetes | CDC

6. Centers for Disease Control and Prevention. United States Diabetes Surveillance System 2023 [updated July 2023; cited 2023 September 27]. Available from: https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html.

7. Centers for Disease Control and Prevention. NCCDPHP's Approach to Social Determinants of Health 2022 [cited 2024 March 20]. Available from: NCCDPHP's Approach to Social Determinants of Health | CDC

8. Community Preventive Services Taskforce. Heart Disease and Stroke Prevention: Interventions Engaging Community Health Workers. March 2015. Available at: HDSP: Community Health Workers | The Community Guide

9. Berini CR, Bonilha HS, Simpson AN. Impact of Community Health Workers on Access to Care for Rural Populations in the United States: A Systematic Review. J Community Health. 2022;47(3):539-53. Epub 20211124. doi: 10.1007/s10900-021-01052-6. PubMed PMID: 34817755.

10. Alsaedi R, McKeirnan K. Literature Review of Type 2 Diabetes Management and Health Literacy. Diabetes Spectrum. 2021;34(4):399-406. doi: 10.2337/ds21-0014.

11. Pasha M, Brewer LC, Sennhauser S, Alsawas M, Murad MH. Health Care Delivery Interventions for Hypertension Management in Underserved Populations in the United States: A Systematic Review. Hypertension. 2021;78(4):955-65. Epub 20210815. doi: 10.1161/HYPERTENSIONAHA.120.15946. PubMed PMID: 34397275.

12. Terens N, Vecchi S, Bargagli AM, Agabiti N, Mitrova Z, Amato L, Davoli M. Quality improvement strategies at primary care level to reduce inequalities in diabetes care: an equity-oriented systematic review. BMC Endocr Disord. 2018;18(1):31. Epub 20180529. doi:

10.1186/s12902-018-0260-4. PubMed PMID: 29843692; PubMed Central PMCID: PMCPMC5975519.

13. Gunderson JM, Wieland ML, Quirindongo-Cedeno O, Asiedu GB, Ridgeway JL, O'Brien MW, et al. Community Health Workers as an Extension of Care Coordination in Primary Care: A Community-Based Cosupervisory Model. J Ambul Care Manage. 2018;41(4):333-40. doi: 10.1097/jac.0000000000000255. PubMed PMID: 30015685; PubMed Central PMCID: PMCPMC6112848.

14. Johnson PJ, O'Brien M, Orionzi D, Trahan L, Rockwood T. Pilot of Community-Based Diabetes Self-Management Support for Patients at an Urban Primary Care Clinic. Diabetes Spectr. 2019;32(2):157-63. doi: 10.2337/ds18-0040. PubMed PMID: 31168288; PubMed Central PMCID: PMCPMC6528400.

15. Lundeen EA, Siegel KR, Calhoun H, Kim SA, Garcia SP, Hoeting NM, et al. Clinical-Community Partnerships to Identify Patients With Food Insecurity and Address Food Needs. Prev Chronic Dis. 2017;14:E113. Epub 20171116. doi: 10.5888/pcd14.170343. PubMed PMID: 29144894; PubMed Central PMCID: PMCPMC5695644.

16. DiDonato KL, May JR, Lindsey CC. Impact of wellness coaching and monitoring services provided in a community pharmacy. Journal of the American Pharmacists Association. 2013;53(1):14-21. doi: https://doi.org/10.1331/JAPhA.2013.11227.

17. Rosenthal M, Ward LM, Teng J, Haines S. Weight management counselling among community pharmacists: a scoping review. International Journal of Pharmacy Practice. 2018;26(6):475-84. doi: 10.1111/ijpp.12453.

18. Newman TV, San-Juan-Rodriguez A, Parekh N, Swart ECS, Klein-Fedyshin M, Shrank WH, Hernandez I. Impact of community pharmacist-led interventions in chronic disease management on clinical, utilization, and economic outcomes: An umbrella review. Research in Social and Administrative Pharmacy. 2020;16(9):1155-65. doi: https://doi.org/10.1016/j.sapharm.2019.12.016.

19. Singh P, LeBlanc P, King-Shier K. Interventions to Improve Medication Adherence in Ethnically Diverse Patients: A Narrative Systematic Review. J Transcult Nurs. 2021;32(5):600-13. Epub 20210527. doi: 10.1177/10436596211017971. PubMed PMID: 34041976.

20. Yu SWY, Hill C, Ricks ML, Bennet J, Oriol NE. The scope and impact of mobile health clinics in the United States: a literature review. Int J Equity Health. 2017;16(1):178. Epub 20171005. doi: 10.1186/s12939-017-0671-2. PubMed PMID: 28982362; PubMed Central PMCID: PMCPMC5629787.

21. Centers for Disease Control and Prevention (CDC), RTI International. NCCDPHP Social Determinants of Health Environmental Scan: Executive Summary. Research Triangle Park, NC 27709: (NCCDPHP) NCfCDPaHP; 2023 September. Report No.

22. Ransome Y, Valido AD, Espelage DL, Clements GL, Harrell C, Eckel C, et al. A systematic review of how social connectedness influences associations between racism and discrimination on health outcomes. Epidemiol Rev. 2023;45(1):44-62. doi: 10.1093/epirev/mxad009. PubMed PMID: 37477041; PubMed Central PMCID: PMCPMC10748800.

23. Holt-Lunstad J. Social Connection as a Public Health Issue: The Evidence and a Systemic Framework for Prioritizing the "Social" in Social Determinants of Health. Annu Rev Public Health. 2022;43:193-213. Epub 20220112. doi: 10.1146/annurev-publhealth-052020-110732. PubMed PMID: 35021021.

24. Town M, Eke P, Zhao G, Thomas CW, Hsia J, Pierannunzi C, Hacker K. Racial and Ethnic Differences in Social Determinants of Health and Health-Related Social Needs Among Adults - Behavioral Risk Factor Surveillance System, United States, 2022. MMWR Morb Mortal Wkly Rep. 2024;73(9):204-8. Epub 20240307. doi: 10.15585/mmwr.mm7309a3. PubMed PMID: 38451870; PubMed Central PMCID: PMCPMC10932584.

25. Bruss KV, Seth P, Zhao G. Loneliness, Lack of Social and Emotional Support, and Mental Health Issues - United States, 2022. MMWR Morb Mortal Wkly Rep. 2024;73(24):539-45. Epub 20240620. doi: 10.15585/mmwr.mm7324a1. PubMed PMID: 38900690; PubMed Central PMCID: PMCPMC11199020.

26. Chen Y, Xue H, Ai S, Liu Y, Nie Y, Ai QH, et al. Trajectories of social isolation and loneliness and the risk of incident type 2 diabetes mellitus across genetic risk score. Diabetes Metab. 2024;50(3):101526. Epub 20240306. doi: 10.1016/j.diabet.2024.101526. PubMed PMID: 38458351.

27. Zhang Y, Liu M, Zhou C, Ye Z, Zhang Y, Yang S, et al. Social isolation, loneliness, and the risk of incident type 2 diabetes mellitus by glycemic status. Diabetes Metab. 2024;50(2):101517. Epub 20240120. doi: 10.1016/j.diabet.2024.101517. PubMed PMID: 38253174.

28. Liang YY, Chen Y, Feng H, Xue H, Nie Y, Ai QH, et al. Social isolation, loneliness and subsequent risk of major adverse cardiovascular events among individuals with type 2 diabetes mellitus. Gen Psychiatr. 2023;36(6):e101153. Epub 20231227. doi: 10.1136/gpsych-2023-101153. PubMed PMID: 38170087; PubMed Central PMCID: PMCPMC10759055.

29. Martino J, Pegg J, Frates EP. The Connection Prescription: Using the Power of Social Interactions and the Deep Desire for Connectedness to Empower Health and Wellness. Am J Lifestyle Med. 2017;11(6):466-75. Epub 20151007. doi: 10.1177/1559827615608788. PubMed PMID: 30202372; PubMed Central PMCID: PMCPMC6125010.

30. National Academies of Sciences, Engineering, and Medicine; Division of Behavioral and Social Sciences and Education; Health and Medicine Division; Board on Behavioral, Cognitive, and Sensory Sciences; Board on Health Sciences Policy; Committee on the Health and Medical Dimensions of Social Isolation and Loneliness in Older Adults. Social Isolation and Loneliness in Older Adults: Opportunities for the Health Care System. Washington (DC): National Academies Press (US); 2020 Feb 27. PMID: 32510896.

31. Office of the Surgeon G. Publications and Reports of the Surgeon General. Our Epidemic of Loneliness and Isolation: The US Surgeon General's Advisory on the Healing Effects of Social Connection and Community. Washington (DC): US Department of Health and Human Services; 2023.

32. Hansen T, Nes RB, Hynek K, Nilsen TS, Reneflot A, Stene-Larsen K, et al. Tackling social disconnection: an umbrella review of RCT-based interventions targeting social isolation

and loneliness. BMC Public Health. 2024;24(1):1917. Epub 20240717. doi: 10.1186/s12889-024-19396-8. PubMed PMID: 39020331; PubMed Central PMCID: PMCPMC11256365.

33. Schoenmakers EC, Lasgaard M, McHugh Power J. Guidelines for evaluating and reporting social isolation and loneliness interventions. J Health Psychol. 2024:13591053241238127. Epub 20240325. doi: 10.1177/13591053241238127. PubMed PMID: 38527950.

Healthy People 2030 and other National Strategic Priorities

Reduce the number of diabetes cases diagnosed yearly. D01

Reduce the rate of death from any cause in adults with diabetes. D-09

Reduce the rate of foot and leg amputations in adults with diabetes. D-08

Increase the proportion of adults with diabetes using insulin who monitor their blood sugar daily — D-07

Increase the proportion of adults with diabetes who get a yearly urinary albumin test — D-05

Increase the proportion of adults with diabetes who have a yearly eye exam — D-04

Increase the proportion of eligible people completing CDC-recognized type 2 diabetes prevention programs — D-D01

Increase the proportion of people with diabetes who get formal diabetes education — D-06

Reduce the proportion of adults with diabetes who have an A1c value above 9 percent — D-03

Reduce the rate of hospital admissions for diabetes among older adults — OA-5

Reduce the proportion of adults who don't know they have prediabetes — D-02

May also address:

Reduce the proportion of people who can't get medical care when they need it — AHS-04

Increase the proportion of adults who get recommended evidence-based preventive health care — AHS-08

Increase the proportion of adults with depression who get treatment — MHMD-05

Increase the proportion of adults with serious mental illness who get treatment — MHMD-04

Public Health Impact

Research supported by this NOFO will identify effective Community-Clinical Linkage and Social Connectedness programs that generate evidence that can guide public health decisions on how to advance health equity in diabetes and other chronic disease outcomes. Rigorous evaluation research will advance our understanding of what works, for whom, and why. This research will fill important gaps in knowledge about 1) the effectiveness of Community-Clinical Linkage and Social Connectedness programs at reducing disparities in diabetes-related outcomes in economically or socially disadvantaged populations (i.e., people with lower incomes, lower educational attainment, those living in rural or hard-to-reach communities, racial and ethnic minority groups, and persons with disabilities), 2) the resources (e.g. training, personnel, financial) required for implementation and scaling of programs and 3) the mechanisms (e.g.

improving specific social or environmental conditions, mental health, or self-efficacy) by which Community-Clinical Linkage and Social Connectedness programs achieve successful health outcomes and 4) the features that characterize effective programs and specific program elements and strategies that contribute to intervention effectiveness and potential impact on health disparities. The results of funded research under this NOFO will help guide future scaling regarding programs, policies, and practices using Community-Clinical Linkage and Social Connectedness to mitigate observed disparities in diabetes risk factors, incidence, and complications.

Relevant Work

- Scaling the National Diabetes Prevention Program in Underserved Areas: Funding for DP17-1705 | State, Local, and National Partner Diabetes Programs | CDC
- Community Health Workers for COVID Response and Resilient Communities (CCR) https://www.cdc.gov/COVID-community-health-workers/index.html;
- Simulation Model of Interventions Linking Evidence to Social Determinants of Health (SMILES)
- Health Promotion and Disease Prevention Research Centers (RFA-DP-24-004)
- Addressing Conditions to Improve Population Health (ACTion; RFA-DP-23-0058: https://www.cdc.gov/addressing-sdoh-chronic-disease/about/action-funding-awardees.html

2. Approach

General Approach

The purpose of this NOFO is to support evaluation of the effectiveness of existing Community-Clinical Linkage or Social Connectedness programs to reduce disparities in diabetes risk factors, incidence, or complications. Additionally, research supported by this NOFO will assess how various mechanisms and intermediate program outcomes (e.g., improving specific social or environmental conditions, mental health, or self-efficacy) will impact diabetes outcomes. This NOFO is not intended to fund the initiation of new programs or interventions, cross-sectional studies, or studies assessing a program without an appropriate comparison group.

Investigators will evaluate one or more existing Community-Clinical Linkage or Social Connectedness program(s) as identified in their application. For either Community-Clinical Linkage or Social Connectedness programs to be evaluated, applicants are expected to demonstrate active cooperation with the organization implementing the program to be evaluated as demonstrated by a signed letter of support specifying that program has not been evaluated previously regarding the study outcomes being assessed in the proposed research.

Applicants are expected to also identify one or more priority populations among program participants with high prevalence of diabetes, diabetes complications, or their risk factors such as historically socially disadvantaged subgroups (i.e. people with lower incomes, lower educational attainment, those living in rural or hard-to-reach communities, racial and ethnic minority groups, and people with disabilities). Through a letter of support, applicants are expected to also demonstrate cooperation with organizations that are representative of the identified priority populations, or other organizations that have a demonstrated record of, or a historical commitment to, serving each identified priority population that is the focus of proposed study.

The existing Community-Clinical Linkage or Social Connectedness program(s) to be evaluated are expected to be identified in the application and are expected to reasonably be expected to affect behaviors relevant to diabetes risk or risk factors for diabetes complications. The programs are expected to be fully enacted and in place for a minimum of 1 year to ensure the intervention is sustainable. A minimum of one year of follow-up time for outcome data after program exposure are expected to be available at the start of the period of performance for the proposed study population. Evaluation of innovative programs that have been culturally adapted or tailored to fit the cultural identifies of their populations and/or settings and interventions that have potential generalizability and feasibility to be adopted in other places or populations is encouraged.

Community-Clinical Linkage Program Characteristics and Research Priorities

Community-Clinical Linkage programs to be evaluated are expected to address both medical needs and social factors such as safe and stable housing, access to nutritious food, reliable transportation, employment and financial security, discrimination, and education. They may be administered by health systems, public health agencies, local governments, community organizations or other entities and may focus on populations at risk for diabetes, those living with diabetes, or both. Programs may use referral networks, community health workers (CHWs), patient navigators, mobile health clinics, community pharmacies or novel health promotion locations, referral programs, or other means to connect populations with medical and community services.

Community-Clinical Linkage research priorities for funding include:

1. Research that assesses the impact of expanding services and support provided by health professionals, such as CHWs, to population groups and in settings (e.g., rural settings, faith-based settings, etc.) with disparities in access to and quality of care.

2. Research on how to optimize interventions integrating health-related social needs into clinical practice and the pathways and characteristics that make the intervention effective.

3. Research assessing the effectiveness and feasibility of service delivery interventions, such as mobile health clinics and interventions at community pharmacies or novel community locations on short- and long-term diabetes outcomes.

Social Connectedness Program Characteristics and Research Priorities

Social Connectedness programs to be evaluated are expected to include interventions targeted for chronic disease management, prevention, or health promotion that address social isolation or loneliness among people at risk for diabetes or living with diabetes. These may include individual and group level interventions (i.e., support groups or group memberships) that encourage social connection as one of the strategies used to promote health, belonging, and wellbeing (e.g., book clubs, walking groups, volunteerism, workout classes). Programs may include activities such as team building exercises or small group discussions, rather than didactic education, or provide guidance to help people build social networks and support. Programs may be administered by health systems, managed care organizations, workplaces, community organizations, local governments, or other entities and are expected to be reasonably expected to

improve social connection and decrease feelings of loneliness or social isolation related to health outcomes.

Social Connectedness research priorities for funding include:

1. Assessing the effectiveness of digital interventions and strategies on Social Connectedness and their impact on diabetes outcomes.

2. Comparative effectiveness research to understand which intervention strategies are most effective for promoting social engagement (e.g., psychological, group exercise, skills training, health education, peer support) and to identify the most-effective modes of delivery for interventions that promote social engagement component (e.g., individual, group, community-based, technology-based, animal-assisted) and impact diabetes outcomes.

3. Research that helps to improve understanding of the processes, effectiveness, and impacts of Social Connectedness program interventions on diabetes outcomes for a diverse range of populations that are disproportionately at risk for isolation and limited Social Connectedness, including individuals living with physical and mental disabilities, individuals living with other chronic conditions, rural-residing individuals, individuals with low income, individuals that identify as LGBTQIA+, and population groups based on constructs of race and ethnicity that disproportionately experience risk factors for diabetes.

4. Research that expands the knowledge base on Social Connectedness interventions that focus on prevention of mental and physical illness (e.g., diabetes) in youth and adolescents.

Analytic Approach and Data Considerations

Studies are expected to use rigorous longitudinal research designs such as natural experiments or quasi-experimental designs with concurrent control conditions or interrupted time series designs. Investigators are particularly encouraged to identify opportunistic, natural experiments wherein accessible comparable control data can be assembled and confounders and biases can be limited through study design, sample selection, and statistical analysis. Control populations identified are expected to reasonably match the exposed study population regarding demographic (age, sex, race, and ethnicity), socioeconomic status, and health parameters (e.g., similar prevalence of comorbidities or risk of diabetes outcomes being assessed). If interrupted time series or similar study designs are utilized without a separate control population, applicants are expected to describe how an appropriate control condition will be used to allow valid inferences regarding the effect of the program.

Applicants are expected to demonstrate access to relevant data on program attributes, process measures, and diabetes-related health outcomes for the study population exposed to the program being evaluated along with comparable control populations as evidenced by signed data-use or data-sharing agreements. Applicants are expected to demonstrate that available data provides sufficient statistical power to reasonably detect selected study outcomes. Data sources may include survey data, medical information systems such as electronic medical records, nontraditional sources, and cohort data. Data elements are expected to also include measures of exposure to Community-Clinical Linkage or Social Connectedness program being evaluated, demographic information to identify the population of interest, and other socioeconomic or potentially confounding factors. If programmatic exposure, sociodemographic, and/or diabetes outcome data are derived from separate datasets, access to each dataset required are expected to be demonstrated with data-use or sharing agreements and feasible methods for linking the

datasets are expected to be provided. Applicants are expected to demonstrate access to or ability to collect data on intermediate outcome factors (changes in social needs, mental health, diabetes distress, etc.) and program characteristics that help to explain the mechanisms by which Community-Clinical Linkage or Social Connectedness programs impact diabetes outcomes.

Other Approach Considerations

For all research proposals, applicants are expected to:

- Establish goals and objectives that are realistic, measurable, and time-oriented for all phases of the project.
- Develop a research protocol involving human subjects for Institutional Review Board (IRB) review and approval by all cooperating institutions participating in the research project.
- Identify one or more research gap or priority that the project aims to address.
- Engage community-level partners (including individuals with lived experience and patients, where applicable) in their research process (planning and execution) and ensure that partners support the selected study outcomes. Include a letter of support from community-based organizations or other organizations that are representative of the identified priority populations, or other organizations that have a demonstrated record of, or a historical commitment to, serving each identified priority population(s) that is the focus of proposed study.
- Utilize existing data on exposure and outcomes at the outset of the funding period.
- Develop, design, and pilot research protocols and instruments and conduct appropriate data management procedures when applicable.
- Describe plans to analyze data and disseminate findings in peer-reviewed journals and presentations at scientific conferences and other meetings.

Objectives/Outcomes

Applicants are expected to complete rigorous evaluation or comparative effectiveness research studies of existing Community-Clinical Linkage or Social Connectedness programs aimed at reducing health disparities in diabetes. Applicants are expected to produce written outputs such as journal papers, conference presentations, and translational guides describing the results of studies undertaken as part of the cooperative agreement. Specific objectives are to:

1. Assess the effectiveness, comparative effectiveness, and/or cost-effectiveness of existing programs on disparities in diabetes risk factors, incidence, treatment, and/or complications, presenting findings as manuscripts in peer-reviewed journals and as abstracts at academic conferences.
2. Investigate the mechanisms and intermediate outcomes by which Community-Clinical Linkage or Social Connectedness programs achieve successful health outcomes and the features that characterize effective programs.
3. Determine the successes and challenges in program implementation, utilization, and usability for one or more disproportionately affected groups to inform recommendations for strategies, resources, and/or technical support needed for successful implementation and future scaling of interventions.

4. Determine the co-benefits, adverse effects, and unintentional consequences of programs that may inform scaling of interventions.

Population of Focus

The programs to be evaluated are expected to include subpopulations of program participants where known disparities in diabetes outcomes exist (e.g., people with lower incomes, people with lower educational attainment, those living in rural or hard-to-reach communities, racial and ethnic minority groups, sexual/gender minority groups, people with disabilities, etc.).

Collaboration/Partnerships

For either Community-Clinical Linkage or Social Connectedness programs to be evaluated, applicants are expected to demonstrate active cooperation with the organization implementing the program to be evaluated as demonstrated by a signed letter of support specifying that program has not been evaluated previously regarding the study outcomes being assessed in the proposed research. Applicants are expected to partner with community organizations or other organizations that represent or advocate for the communities or groups that are the focus of the proposed research of diabetes disparities. Applicants are also encouraged to form or expand innovative collaborations/partnerships with researchers or agencies (e.g., community-based organizations, local governments, employers, etc.) that have established interests in reducing the disparities in chronic disease or that do not have established interests but nonetheless may influence key levers in reducing these disparities (such as influencing food or physical activity patterns). Such relationships could be useful for planning and/or execution of their focused research plans. Where applicable, applicants are encouraged to also engage with program participants in their research process (including planning and execution) and employ a community-based participatory research (CBPR) approach. Through these partnerships, researchers can rigorously evaluate programs to determine their effectiveness in reducing diabetes disparities, build capacity of community organizations to prevent chronic disease, develop approaches that are scalable, and disseminate/translate effective community diabetes prevention approaches that can inform national prevention efforts.

Evaluation/Performance Measurement

Applicants should provide a timeline of key milestones anticipated during each project year. During the first project year, evaluation will be based upon and measured by the refinements made to study design, analytic protocol, commitments made to professional staffing and potential collaborators, and updated reviews of existing data that are relevant to the selected program being evaluated. In subsequent years, success should be measured by performance measures demonstrating the execution of the research plan, procurement and/or collection of key data, appropriate validation of data elements, timeliness of data analyses, dissemination of findings in the form of peer-reviewed publications and scientific presentations, and participation in the collaborative, multicenter research network. Evaluation should include assessment of the degree to which the research fills important research gaps and assesses outcomes of important health impacts, including chronic disease risk.

Please include the Evaluation Plan in the R&R Other Project Information Form under item 12. Other Attachments.

Translation Plan

Study findings are expected to be presented at professional meetings and at formal briefings for health and policy makers. Results should be submitted to peer-reviewed journals and aspects of the work disseminated through diverse media such as a study website and policy briefs.

Please include the Translation Plan in the R&R Other Project Information Form under item 12. Other Attachments.

3. Funding Strategy

N/A

Section II. Award Information

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

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

Estimated Total Funding:
$3,150,000
Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Throughout the period of performance, CDC's commitment to continuation of awards will be conditional on 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.

Anticipated Number of Awards:
3
Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling:
$350,000
Per Budget Period

Award Floor:
$0
Per Budget Period

Total Period of Performance Length:
3 year(s)

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

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

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

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

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

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

23 (Small businesses)

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

3. Additional Information on Eligibility

N/A

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Applications that do not meet the following criteria will be considered nonresponsive and will not be forwarded for peer review.

1. Applicants must provide a signed memorandum of understanding or data use agreement that demonstrates continuous access to existing data sets and/or data systems needed to accomplish study objectives and allows unrestricted publication of findings regardless of study outcomes. The signed memorandum of understanding or data use agreement should also state that a minimum of 1 year of follow-up data will be available at the start of the period of performance. The signed memorandum of understanding or data use agreement must be included in the Appendix section of the application.
2. Applicants must identify an existing Community-Clinical Linkage or Social Connectedness program that will be evaluated. The program must be indicated on the Specific Aims page of the application.
3. Applicants must provide a letter of support from the institution conducting the Community-Clinical Linkage or Social Connectedness program proposed for evaluation specifying that program has not had a rigorous evaluation conducted regarding the study outcomes being assessed in the proposed research. The letter should also demonstrate that the program to be evaluated has been in operation for a minimum of 1 year. The letter of support must be included in the PHS 398 Research Plan's Other Research Plan Section in item 9. Letters of Support.
4. Applicants must provide a signed letter of support from one or more community-based organizations or other organizations that have a demonstrated record of, or a historical commitment to serving, each identified priority population of program participants that is the focus of proposed study (e.g., people from racial and ethnic minority groups or rural areas and people with lower incomes, education, or disability). The letter of support must be included in the PHS 398 Research Plan's Other Research Plan Section in item 9. Letters of Support.
5. Requested budget (direct and indirect) for the first budget year must not exceed the funding level ceiling of $350,000.

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 Unique Entity Identifier (UEI) number in order to begin each of the following registrations.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI replaced the Data Universal Numbering System (DUNS) and is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

(Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: NCAGE Tool / Products / NCS Help Center (nato.int).

System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, SAM.gov.

Grants.gov

eRA Commons

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

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

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

All applicant organizations **must obtain** a Unique Entity Identifier (UEI) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The UEI number is a twelve-digit number assigned by SAM.gov. An AOR should be consulted to determine the appropriate number. If the organization does not have a UEI number, an AOR should register through SAM.gov. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a UEI number.

Additionally, 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.gov 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 SAM.gov and the SAM.gov Knowledge Base.

If an award is granted, the recipient organization **must** notify potential sub-recipients that no

organization may receive a subaward under the grant unless the organization has provided its UEI number to the recipient organization.

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

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. CDC does not make awards to individuals directly. Individuals from organizations that are uniquely prepared to examine research relevant to undeserved groups, including sexual orientation and gender identity minorities as well as individuals with disabilities are always encouraged to apply.

9. Cost Sharing

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

10. Number of Applications

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

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

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

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

2. Content and Form of Application Submission

Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

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

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

Please note: 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.

3. Letter of Intent

Due Date for Letter Of Intent 12/02/2024

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

By the date listed above and in Part 1. Overview Information, prospective applicants are encouraged to submit a letter of intent that includes the following information:

- Name of the Applicant
- Descriptive title of proposed research
- PD(s)/PI(s) contact information (name, address, and telephone number)
- Names of other key personnel
- Names of participating institutions
- Include the number and title of this funding opportunity in the subject line.

The letter should be emailed to:

Celeste Sanders, PhD

Scientific Program Official

Email: CSanders4@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 at How to Apply - Application Guide for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).

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

1. **Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the NOFO.
2. **Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. **Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation, and Approach. Describe the proposed research plan, including staffing and timeline.
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. **Other Plan(s)**
12. **Authentication of Key Biological and/or Chemical Resources**
13. **Appendix**

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

Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Other Plan(s) 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 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);
- A statement (required) of any limitations you may encounter with sharing data collected or generated under this award with CDC (such as legal, regulatory, policy, or technical concerns);
- 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).

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

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/nccdphp/dch/media/files/Data-Management-Plan-template.docx

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

Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

Research Plan

Study Setting and Context

- In specific aims, identify the existing Community-Clinical Linkage or Social Connectedness program that will be evaluated.
- If the proposed research addresses a specific priority listed in the approach section of this NOFO, identify which research priority will be addressed in the specific aims.
- Explain where evidence is lacking on the program to be evaluated.
- Provide justification of the choice of the proposed program for a natural experiments study and justification of the anticipated effect on diabetes outcomes or risk factors.
- Describe the size and demographic characteristics of the populations included in the proposed research study. If the study includes subpopulation analyses, provide a description.
- Identify one or more population(s) of focus experiencing disparities in diabetes outcomes that will be impacted by the Community-Clinical Linkage or Social Connectedness program proposed for evaluation.

- Describe the potential value of the proposed project to reduce health disparities in the population(s) of focus.
- Describe disparities in diabetes outcomes or risk factors to be addressed, for example, which outcomes or risk factors in which subgroups of the population are affected by the program.
- Describe how health disparities are impacted by the program to be evaluated. Describe previous efforts to address these outcomes or risks factors within the population of focus and the remaining knowledge gaps.
- Describe the aspects of health equity addressed by the intervention and describe how these factors affect diabetes disparities in the population group being studied.
- Discuss the potential generalizability of the findings.

Study Methods

Provide a description of the relevant study methods which includes the following:

- List research/study objectives and describe how they relate to diabetes risk and outcomes in the population impacted by the program.
- Describe the specific outcomes and any risk or protective factors or other proposed moderators or mediators to be examined.
- Provide the hypotheses to be tested related to program effectiveness to reduce health disparities in diabetes outcomes in the United States.
- Describe key sources of data, specifically:
    - Existing data sets and data systems that permit the assessment of health impacts of the selected program.
    - Any data that currently exists or may be collected on mechanisms and/or program attributes that may mediate program effects on study outcomes.
    - How the data are appropriate for documenting the effects of the program and likely to show the expected changes in the time available.
    - The amount follow-up time after program exposure available at the start of and during the period of performance for the proposed study population
- Provide a data analysis plan including statistical methods, sample sizes, and power calculations for evaluating the program in the population of focus. The study should be powered to detect change in health disparities in diabetes outcomes or risk factors. Include documentation (in the form of a table) showing that the dataset for the proposed study meets a minimum study sample size to detect associations with the proposed at outcome with ≥80% statistical power. This evidence should be placed as an Appendix in the application.
- If the applicant is proposing to evaluate a program that is part of a broader, multi-level prevention effort, describe how the evaluation design will disentangle impacts that might be due to other prevention activities and allow conclusions to be drawn about how changes in two or more outcomes can be attributed independently to the program.

Study Dissemination and Impact

- Describe plans for disseminating study findings at professional meetings, at formal briefings for health and policy makers, and/or to the community residents where the program was implemented.
- Describe plans for the submission of findings for publication in peer-reviewed journals and other venues to inform future policy, environmental or systems change to reduce health disparities in chronic diseases.

Staffing and Management

- Provide a staffing and management plan that defines the roles, responsibilities, and qualifications of the team and expected contributions of key/collaborative partners.
- Research Team: Describe the experience of the principal investigator and co-investigators in undertaking complex public health-related or policy studies that (1) make use of data from diverse data sources, (2) are multi-disciplinary (including, but not limited to implementation science, health disparities, epidemiology, public policy, health communications, economics, individual and organizational behavioral science, statistics), and (3) result in peer-reviewed journal publications. Applicant's research team should include investigators with expertise in health equity and SDOH research.
- Principal Investigator: Describe the principal investigator's (1) expertise, (2) established leadership in designing and conducting complex studies that make use of multiple sources of data, (3) track record of publishing study findings in peer-reviewed journals and making presentations at professional and scientific conferences and policy forums, and (4) commitment to collaborate and contribute to a multi-center research network, including participating in study meetings as well as periodic teleconferences each year. Specify the percentage of time that will be committed to this research program by the PI.
- Other Researchers: For each proposed co-investigator and other members of the research team, describe the following:(1) the person's expertise, (2) previous experience and contributions to relevant complex studies, including their publications in peer-reviewed journals and presentations made at professional and scientific conferences, and (3) specify the percentage of time that will be committed to this research program.
- Provide a management plan, which describes:
    - The staffing plan for the 3-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.
    - If a position is yet to be filled, the position description and proposed timeline to fill the position in an Appendix.
    - 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.

Memorandum of Understand/Data Use Agreement and Letters of Support

- Provide a signed memorandum of understanding or data use agreement that demonstrates continuous access to existing data sets and/or data systems needed to accomplish study

objectives and allows unrestricted publication of findings regardless of study outcomes as an Appendix in the application. The signed memorandum of understanding or data use agreement should also state that a minimum of 1 year of follow-up data will be available at the start of the period of performance. The signed memorandum of understanding or data use agreement must be included in the Appendix section of the application.

- Provide a letter of support from the institution conducting the Community-Clinical Linkage or Social Connectedness program proposed for evaluation specifying that program has not been evaluated previously regarding the study outcomes being assessed in the proposed research. The letter should also demonstrate that the program to be evaluated has been in operation for a minimum of 1 year. The letter of support must be included in the PHS 398 Research Plan's Other Research Plan Section in item 9. Letters of Support.
- Applicants must provide a letter of support from one or more community-based organizations or other organizations that have a demonstrated record of, or a historical commitment to, serving each identified priority population of program participants that are the focus of proposed study (e.g., people from racial and ethnic minority groups or rural areas and people with lower incomes, education, or disability). The letter of support must be included in the PHS 398 Research Plan's Other Research Plan Section in item 9. Letters of Support.
- Provide a letter of support from any other partner organizations that will be involved in the activities proposed in the application. Letters should (1) describe prior collaborations with the applicant organization, if any, and (2) specify the contributions that the partner organization is committed to make to the proposed research, including the provision of necessary data. The letter of support must be included in the PHS 398 Research Plan's Other Research Plan Section in item 9. Letters of Support.

Budget

- Include in the budget the cost of travel to attend one in-person annual meeting of funded study sites at CDC in Atlanta.

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 12 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 20 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

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

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

Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

9. Submission Dates & Times

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

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

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

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

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

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

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726

https://www.grants.gov/support
support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

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

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

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

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

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

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

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

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

Due Date for Applications 01/06/2025

Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.

10. Funding Restrictions

Expanded Authority:

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

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

Public Health Data:

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

Data Management Plan:

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Other Plan(s) section of the PHS 398 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, but not limited to, any statutory limitations prohibiting data sharing, privacy and confidentiality considerations, embargo issues).

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.

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

Human Subjects:

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

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

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

11. Intergovernmental Review

This NOFO is not subject to executive order 12372, Intergovernmental Review of Federal Programs. No action is needed.

12. Other Submission Requirements and Information

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."

Include in the budget the cost of travel to attend one in-person annual meeting of funded study sites at CDC in Atlanta.

Application Submission

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

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

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

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

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

The applicant organization must ensure that the UEI 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/divisions-offices/index.html), 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 public health be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

- If the applicant proposes evaluation of a Community-Clinical Linkage program, does the program address both medical needs and social factors such as safe and stable housing, access to nutritious food, reliable transportation, employment and financial security, discrimination, and education?
- If the applicant proposes evaluation of a Social Connectedness program, is the program targeted for chronic disease management, prevention, or health promotion and address social isolation or loneliness among people at risk for diabetes or living with diabetes?
- Does the applicant provide justification of the choice of the proposed program for a natural experiments study and justification of the anticipated effect on diabetes outcomes or risk factors and where evidence is lacking on the program type to be evaluated?
- Does the applicant identify one or more population(s) of focus experiencing disparities in diabetes outcomes that will be impacted by the Community-Clinical Linkage or Social Connectedness program proposed for evaluation?
- Does the applicant describe the potential value of the proposed project to reduce health disparities in the population(s) of focus. Does the applicant describe the potential or actual impact of the research on public health in the US?
- To what extent will the work be influential in that it will lead others to investigate the problem, open new areas of research, or change the scientific approach or public health practice, and how will this improve and be of value to public health?
- Does the proposed research address program interventions that may be applied to broad segments of the population and are they potentially generalizable to diverse settings?

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?

- To what extent do the PI and/or co-investigator or other members of the research team have ongoing record of success in conducting research or rigorous evaluation of Social Connectedness, Community-Clinical Linkage, or similar programs being examined by the proposed research?
- To what extent is there evidence of past collaboration between the proposed research team and external partners, and inclusion of community members or program participants to co-design the project, to support the success of the proposed research?
- To what extent does the application demonstrate that the research team has the skills, experience, and sufficiently devoted time to complete the proposed activities within the period of performance?

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?

- Does the research evaluate a program for which evidence of effectiveness in reducing health disparities in diabetes outcomes, risk factors, or behaviors in the population of focus is lacking?
- Is the program selected for evaluation been culturally adapted or tailored to fit the cultural identifies of their populations?

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 research project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?

If the project involves human subjects and/or 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?

If applicable, how will populations with health disparities be considered and addressed in the design and implementation of the proposed research activities?

- Has the program selected for evaluation been in place long enough to provide evidence that the program is sustainable?
- Does the length of follow-up time of outcome data available for analysis during the period of performance allow assessment of medium (2-4 years) or long-term (≥5 years) diabetes-related outcomes?
- Are the proposed analytic methods appropriate to assess the effect of the program on proposed outcomes in a longitudinal manner? Do the methods include an appropriate control population or condition?
- Are the proposed outcomes measured before and after exposure to the evaluated program so that they may reasonably be expected to be impacted by program participation?
- Do the proposed study design and analytic methods sufficiently control for potential confounding?
- Does the applicant demonstrate the ability to access the necessary data for the evaluation of the selected program(s), including disaggregated subgroup data, to understand if disparities are lessened? Are these data appropriate for documenting the effects of the program(s) and likely to show the expected changes in the time available?
- Are the outcomes and any risk or protective factors or other proposed moderators or mediators to be examined clearly described, validly measured, and appropriate?

- Does the applicant describe how the study will examine the intermediate outcomes (changes in social needs, mental health, diabetes distress, etc.) and program attributes by which the program impacts diabetes outcomes?
- Does the applicant propose a study with adequate sample size to test the proposed hypotheses, and is the study adequately powered to measure changes in disparities between subgroups?
    - Does the applicant include documentation (in the form of a table) showing that the dataset for the proposed study meets a minimum sample size to detect associations with the proposed at outcomes with ≥80% statistical power?
    - To what extent does the application specify strategies to achieve the projected sample size? Are appropriate strategies proposed to assure adequate statistical power?
- If an applicant is proposing to evaluate a program that is part of a broader, multi-level prevention effort, to what extent does the applicant describe the broader effort and how the evaluation design will disentangle impacts that might be due to other prevention activities and allow conclusions to be drawn about how changes in outcomes can be attributed independently to the program?
- If an applicant is proposing to evaluate multiple programs, to what extent does the applicant propose to evaluate each program for its impact on reducing diabetes disparities?

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?

To what extent will findings be disseminated to communities and populations of focus in an appropriate and accessible manner?

- Do the applicants demonstrate innovative collaborations/partnerships with researchers or organizations (e.g., community-based organizations, local governments, employers, etc.) that have established interests in reducing the disparities in chronic disease or that do not have established interests but nonetheless may influence key levers in reducing these disparities (such as influencing food or physical activity patterns)?
- Do applicants propose engagement with community members or program participants in their research process (including planning and execution) and employ a community-based participatory research (CBPR) approach?
- Are all the partnerships necessary to complete the proposed project supported by letters of support (LOS) or memoranda of understanding (MOU)?
- To what extent do the LOS or MOU clearly describe the working relationships between the research institution and all partner organizations? What is the anticipated extent of involvement and scope of work to which the partner is willing to commit to ensure the successful, implementation and evaluation of the proposed program evaluation, including directly providing or facilitating access to relevant implementation or outcome data?

- To what extent will the applicant's organizational support and proposed partnerships to carry out the research activities lead to potential success?

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/additional-requirements/ar-1.html).

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/women/research/index.htm) and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/grants/additional-requirements/ar-28.html).

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

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

protection is proposed.

Dual Use Research of Concern
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

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

3. Additional Review Considerations

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

Applications from Foreign Organizations
N/A

Resource Sharing Plan(s)
Reviewers will comment on whether the Resource Sharing Plan(s) (e.g. Sharing Model Organisms) or the rationale for not sharing the resources, is reasonable.

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 budget preparation guidance for completing a detailed justified budget on the CDC website, at the following Internet address: https://www.cdc.gov/grants/applying/application-resources.html. Following this guidance will also facilitate the review and approval of the budget request of applications selected for award.

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 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.
- Diversity of program types (Social Connectedness and Community-Clinical Linkages) being studied across funded applicants.
- Research that addresses specific priority research areas identified in the Approach section of this NOFO.

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

In accordance with 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM 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 review of risk may impact award eligibility.

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

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under 45 CFR Part 75, subpart F, or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities. Additionally, we may ask for additional information prior to the award based on the results of this risk review.

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

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

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 recipient’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

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

AR-1: Human Subjects Requirements

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

AR-7: Executive Order 12372, Intergovernmental Review of Federal Programs

AR-8: Public Health System Reporting Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2030

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-15: Proof of Non-profit Status

AR-16: Security Clearance Requirement

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

AR-22: Research Integrity

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

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: Research Definition

AR-32: Appropriations Act, General Provisions

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

AR-34: Accessibility Provisions and Non-Discrimination Requirements are incorporated into CDC General Terms and Conditions

AR-36: Certificates of Confidentiality

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

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 applies to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at: https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

Federal Funding Accountability and Transparency Act of 2006: Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

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

Employee Whistleblower Rights and Protections: Employee Whistleblower Rights and Protections: All recipients of an award under this NOFO will be subject to a term and condition that applies the requirements set out in 41 U.S.C. § 4712, "Enhancement of contractor protection from reprisal for disclosure of certain information" and 48 Code of Federal Regulations (CFR) section 3.9 to the award, which includes a requirement that recipients and subrecipients inform employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. § 4712. For more information see: https://oig.hhs.gov/fraud/whistleblower/.

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. Applicants may include reasonable publication costs and costs associated with submission, curation, management of data, and special handling instructions as allowable expenses in all research budgets. 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 without any embargo or delay after publication. Also at the time of submission, Recipient and/or Recipient's submitting author must also post the manuscript through PMC without any embargo or delay after publication. The recipient must obtain prior approval from the CDC for any exception to this provision.

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

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

Dual Use Research of Concern: On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Recipients (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 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 following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and CDC grant administration policies.

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

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/additional-requirements/ar-25.html
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: "This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention". In addition, the PI must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The recipient will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf).
- Develop a Data Management Plan (DMP) prior to the initiation of generating or collecting public health data.

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/additional-requirements/ar-25.html
- Preparing the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed.
- Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
- Assisting the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
- Collaborate with recipients in overall project planning and development, including development and selection of data collection instruments and protocols, and data abstraction forms.
- Review and approve the recipients' proposed staffing plan and proposed subcontracts.

- Assist in development of data analysis plans, analysis, and interpretation of data analysis, both quantitative and qualitative.
- Monitor and evaluate the accomplishments of the project. This will be accomplished through annual in-person meetings of all study site investigators at CDC, telephone calls, and review of technical reports and interim data analyses.

Recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

Additionally, a Scientific Program Officer in the NCCDPHP Extramural Research Program Office and Services (ERPOS) will be responsible for the normal scientific and programmatic stewardship of the award as described below:

- Named in the Notice of Award as the Program Official to provide overall scientific and programmatic stewardship of the award.
- Serve as the primary point of contact for official pre-award activities and for all award-related activities, including an annual review of the recipient's performance as part of the request for continuation application.
- Make recommendations on requests for changes in scope, objectives, and or budgets that deviate from the approved peer-reviewed application.
- Carry out continuous review of all activities to ensure objectives are being met.
- Attend committee meetings and participate in conference calls for the purposes of assessing overall progress, and for program evaluation purposes.
- Monitor performance against approved project objectives.

Areas of Joint Responsibility include:

- Collaborating in the development of human subject research protocols and additional documents for IRB review by all cooperating institutions participating in the project and for OMB review, if needed.
- For applications that are successfully funded under this NOFO, the recipient agrees that upon award, the application and the summary of reviewers' comments for the application may be shared with the CDC staff who will provide technical assistance, 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 submit:

Annual Performance Report (APR)/RPPR is due 120 days before the end of the current budget period, or the date identified in the guidance that CDC distributes. 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.

Annual Federal Financial Report (FFR) SF-425 (Reporting | Grants | CDC) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS **within 90 days after the budget period ends.**

Closeout Reports: a final progress report, invention statement, equipment/inventory report, and the **Final FFR (SF-425)** are required **120 days after the end of the period of performance.**

B. Content of Reports

1. Annual Performance Report (APR)/RPPR: The recipient's continuation application/progress report 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 budget period. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The Final FFR (SF-425) 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.

Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.

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 (SF-425), final progress report, and Final Invention Statement and Certification within 120 days after the end of the period of performance. 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).

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

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

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

Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.

Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the Period of Performance. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.

Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.

Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC-funded activity. Please include any additional dissemination efforts that did or will result from the project.

Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

6. Termination

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

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

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

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

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

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

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

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

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

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal

year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:

“Commodity” means any material, article, supplies, goods, or equipment;

“Foreign government” includes any foreign government entity;

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

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

5) Contents of Reports: The reports must contain:

a. recipient name;

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

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

d. reporting period;

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

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

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

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

Section VII. Agency Contacts

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

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
https://www.grants.gov/support
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
https://www.era.nih.gov/need-help
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time; closed on Federal holidays

Scientific/Research Contact(s)
Celeste Sanders, PhD
Scientific Program Official
Extramural Research Program Operations & Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30341
Email: CSanders4@cdc.gov

Peer Review Contact(s)
Catherine Barrett, Ph.D.
Scientific Review Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
Telephone: (404) 718-7664
Email: ohi6@cdc.gov

Grants Management Contact
Angie N. Willard
Grants Management Officer, Team Lead
Research, Branch 2
CDC/OCOO/OFR/OGS
Telephone: (770) 488-2863 | CDC iPhone: (770) 568-8762
Email: aen4@cdc.gov

Section VIII. Other Information

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

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

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

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