

Centers for Disease Control

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

Packaging and Spreading Proven Pediatric Weight Management Interventions for Use by Low-Income Families

RFA-DP-19-002

Application Due Date: 10/24/2018

Packaging and Spreading Proven Pediatric Weight Management Interventions for Use by Low-Income Families

RFA-DP-19-002

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control

Components of Participating Organizations

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

Notice of Funding Opportunity (NOFO) Title

Packaging and Spreading Proven Pediatric Weight Management Interventions for Use by Low-Income Families

Activity Code

U18 - Research Demonstration--Cooperative Agreements

Amendment I made 10/05/18

- New Risk Assessment Questionnaire requirement in *Section IV. Application and Submission Information - 12. Other Submission Requirements and Information*, is emphasized.
- Definitions for the terms "health care provider" and "community based organization" is added to *Section III. Special Eligibility Requirements*.
- Questions from Potential Applicants and CDC Responses for NOFO DP19-002 Packaging and Spreading Proven Pediatric Weight Management Interventions for Use by Low-Income Families is added to *Section VIII. Other Information.*

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-19-002

Assistance Listings (CFDA) Number(s)

93.349

Category of Funding Activity:

Health

NOFO Purpose

The purpose of this NOFO is to increase the availability and number of packaged effective pediatric weight management interventions (PWMI) that can be used by healthcare, community or public health organizations to serve low-income children and their caregivers. This will be achieved by having researchers take existing evidence based PWMI, and convert them into user-friendly "packaged" materials so that the PWMI can be replicated and pilot tested in real world settings. The demonstration will provide ongoing support to children and families through the PWMI and referral to community-based resources for healthy nutrition and physical activity behaviors. The long-term goal of this NOFO is to increase the access to and uptake of acceptable, effective, and packaged PWMIs by institutions that serve low-income children.

Key Dates

Publication Date:	**To receive notification of any changes to RFA-DP-19-002, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.**
Letter of Intent Due Date: 9/24/2018	**09/24/2018**
Application Due Date: 10/24/2018	**10/24/2018**

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 5:00 PM U.S. Eastern Time. Applications must be submitted using the Application Submission System & Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore identifying issues earlier in the application submission process.

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

Scientific Merit Review: and 12/12/2018	**12/11/2018**
Secondary Review:	**01/23/2019**
Estimated Start Date: 4/1/2019	**04/01/2019**
Expiration Date:	**10/25/2018**
Due Dates for E.O. 12372:	**Executive Order 12372 does not apply to this program.**

Required Application Instructions

ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission

validation of business rules, and preview of the application image used for review). Use of the Grants.gov downloadable Adobe application packages and submission process will still be supported.

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

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

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

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

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

(See Part 2, Section IV, 7. Page Limitations).

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

A link to this FOA will be available at Funding Opportunities Announcements | Chronic Disease Prevention and Health Promotion | CDC

Executive Summary

Purpose. This NOFO will build on prior childhood obesity research demonstration (CORD) projects in implementing a model for reducing childhood obesity among low-income children with overweight or obesity. The demonstration shall provide support to target children and their families to reduce risk factors through the appropriate use of screening, preventive, and management benefits and ongoing community supports. The purpose of this NOFO is to increase the availability and number of packaged effective pediatric weight management interventions (PWMI) that can be used by healthcare, community or public health organizations to serve low-income children and their caregivers. This will be achieved by having researchers take existing evidence based PWMI, and convert them into user-friendly "packaged" materials so that the PWMI can be replicated and pilot tested in real world settings to improve health outcomes, satisfaction, and quality of life. The long-term goal of this NOFO is to increase the access to and uptake of acceptable, effective, and packaged PWMIs by institutions that serve low-income children.

- **Mechanism of Support.** U18 Cooperative Agreement mechanism
- **Funds Available and Anticipated Number of Awards** The estimated total level of funding (direct and indirect for entire project period in dollars) that is available for the NOFO is $12,500,000. Up to 5 awards will be made under this NOFO but the number awarded is contingent upon availability of funds and a sufficient number of meritorious applications. For each awardee, approximately $750,000 will be available per year for Budget Years 1 and 2. Approximately $600,000 will be available for Budget year 3 and

approximately $200,000 will be available per year for Budget Years 4 and 5. These estimates include direct and indirect costs. 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 Project Period.** The estimated total funding (direct and indirect) for the first budget period, 4/1/2019 to 3/31/2020, is $3,750,000. The estimated total funding (direct and indirect) for the entire project period, 4/1/2019 to 3/31/2024 is $12,500,000.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1. are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** Applications may include more than one PI; however, the first PI listed on the application will be the "contact PI" for all correspondence. Any additional PIs are permitted, but would be referred to as Co-PIs.
- **Number of Applications.** Eligible applicant institutions may submit more than one application, provided that each application is scientifically distinct.
- **Application Type.** New
- **Application Materials.** See Section IV.1 for application materials. Please note that Form D is to be used when downloading the application package. http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf%20 ;
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

HEALTHY KIDS Act, Section 2104(a) of the Social Security Act (42 U.S.C. 1397dd(a)), as amended by section 3201(a) of the CHIP and Public Health Funding Extension Act and Section 3003(a) (Childhood Obesity Research Demonstration) and amends Section 1139A(e) of the Social Security Act (42 U.S.C. 1320b–9a(e).

1. Background and Purpose

Childhood overweight and obesity remain a pressing public health concern, affecting approximately 1 in 3 U.S. children aged 2-19 years (1. Hales 2017). In addition, some subgroups such as low-income children experience higher rates (2. Pan 2015). Childhood

obesity is also a condition with serious and costly effects including increased risk for type 2 diabetes, asthma, depression, and bullying (3. Egan 2013, 4. Li 2016, 5. Van Geel 2014, 6. Quek 2017, 7. Liu 2010). Children with obesity are at high risk for continued excess weight and related comorbidities in adulthood (8. Gordon-Larsen 2010). Children and adolescents with obesity have higher total medical expenditures and use more health services and medications compared with children who have a healthy weight (9. Trasande 2009, 10. Finkelstein 2014).

The chronic care model, as described by Wagner et al (11. Wagner 1998), organizes approaches to support chronic disease management. The Obesity Chronic Care Model (12. Dietz 2007) draws from the Wagner model and includes information systems, decision supports, delivery system design and self-management support that centers on patient self-management. This framework focuses on interventions to improve obesity-related behaviors as taking place in three overlapping arenas: (1) the community and its resources and policies; (2) the health care system and payment structures; and (3) the health care provider.

Professional groups and societies, including the American Academy of Pediatrics (AAP), have recommended that health care providers (including physicians, nurses, nurse practitioners, psychologists, dietitians and health coaches) organized as multidisciplinary teams address weight management and lifestyle issues with all pediatric patients on a routine basis (13. Barlow 2007, 14. Daniels 2015). Assessment begins with screening by measuring height and weight and plotting body mass index (BMI). Children with a BMI greater or equal to the 85th percentile for their age and sex should receive counseling interventions tailored to the individual child and family, and staged by the patient's age and degree of excess weight, should utilize motivational interviewing and comprehensive behavioral components. For children with obesity, more intensive intervention programs are required, and may occur both in clinical and community settings.

In 2017 the U.S. Preventive Services Task Force (USPSTF) reviewed the existing literature related to screening and management of childhood obesity. The Task Force recommended that clinicians screen all children aged 6 years and older for obesity by measuring BMI and offer or refer children with obesity to comprehensive, intensive behavioral interventions that are moderate to high intensity (>26 contact hours over 2-12 months) to promote improvements in weight status and improvements in cardiovascular and metabolic risk factors (15. USPSTF 2017). Other groups such as the American Psychological Association and the Endocrine Society have similar Clinical Practice Guidelines stating that clinicians should provide referrals to family-based, multicomponent behavioral interventions, with a minimum of 26 contact hours, initiated at the earliest age possible for children aged 2 to 18 years with overweight or obesity (16. APA 2018 17. Styne 2017).

Despite national recommendations, and supporting scientific evidence, there remain multiple barriers to the operationalization of these recommendations for all children. Performance measure data from the National Committee on Quality Assurance's (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS) indicate that in 2016 the BMI assessment by primary care providers for children 3-17 years old was <70% nationally, and <66% and <58% receive recommended nutrition and physical activity counseling, respectively (18. NCQA 2017). There is little information available on the rate of referral, and successful enrollment in a weight management program, once BMI screening is completed. One study noted that out of >4700 patients referred to a comprehensive weight management clinic 59% never attended a single visit (19. Shaffer 2016). Researchers in Texas looked at the number of children with a

BMI >85th percentile who were eligible for referral into an evidence based pediatric weight management study and found that only 26% of eligible children were referred to the study. Moreover, they found that only 27% of those referred actually enrolled. Enrollment was associated with being Hispanic and a higher severity of obesity illustrating the challenges of referral and enrollment into pediatric weight management interventions (20. Barlow 2017). Low rates of referral to, and attendance in, pediatric weight management programs may be due to a variety of factors. Parental surveys cite referral procedures, costs, logistics, mismatched expectations and child motivation as barriers to completing a referral. (21. Hampl 2013, 22. Kulick 2017). Low rates of referral into programs may also be another reason children are not receiving guideline based care. For example one study found that at the practice level, primary care providers initiate referrals to community-based weight management programs for only 52% of children with obesity without complications and only 66% of children who have obesity with complications (23. Libert 2018). Finally, hospital-based weight management programs are typically limited in number and 52% of registered programs offer low-intensity services that do not meet USPSTF recommendations (24. Kirk 2016).

In 2015 a multidisciplinary group of stakeholders, brought together through the support of the American Academy of Pediatrics (AAP) Institute for Healthy Childhood Weight, The Agency for Healthcare Research, and The Obesity Society, met to discuss how to improve access to evidence based childhood obesity treatment (25. Wifley 2017). The group put forth best practices and concluded that the treatment of obesity does not occur as an acute episode of care, and as such, the chronic care model should be utilized. The group expressed that efforts are needed to accelerate uptake of the USPSTF recommendations by increasing the access and reimbursement to evidence based obesity treatment. These programs would need to integrate the critical components of a family-based pediatric weight management program, the continued cross-sector collaborations to ensure a unified approach, and also have a supportive infrastructure including improved reimbursement for such treatments. National groups have also noted the challenges which weight management programs face in long-term sustainability because many programs or services are not fully reimbursed and/or are currently supported through in-kind or grant funds (26. Children's Hospital Association 2013).

To aid moving research into practice the CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) developed the Knowledge to Action (K2A) framework (27. https://www.cdc.gov/chronicdisease/pdf/k2a-framework-6-2015.pdf). This framework outlines the process necessary to move from discovery into action through the translation of evidence based programs and practices into routine public health and healthcare practice. One way of translating interventions is by packaging intervention protocols and materials into user-friendly materials. These packaged interventions improve the capacity of others to replicate the intervention. This model has been used extensively by CDC for HIV prevention (28. Collins 2011).

Currently, there are a small number of pediatric weight management programs with low attrition, that have been shown to effectively improve children's weight and health via rigorous testing such as randomized controlled clinical trials (RCTs) (25. Wilfley 2017, 15. USPSTF 2017). There are a few PWMIs that that: 1) meet the USPSTF recommendations for dose and intensity, and are feasible and acceptable to low-income families, and 2) are "packaged". To address the current gap in the care and treatment of children who are overweight or who have obesity, more PWMIs that have been research tested and rigorously evaluated are needed to

package into programs and be pilot tested to help children and families struggling with obesity.

Purpose:

The purpose of this NOFO is to increase the availability and number of packaged effective PWMIs that can be used by healthcare, community or public health organizations to serve low-income children and their caregivers. Packaging consists of researchers taking an existing evidence based PWMI, and converting into user-friendly "packaged" materials, meaning that they contain all materials necessary, for easy, efficient and complete replication by clinical or community entities. Grantees will then replicate pilot test this PWMI package in real world settings to improve health outcomes, satisfaction, and quality of life. The long-term goal of this NOFO is to increase the access to and uptake of acceptable, effective, and packaged PWMIs by institutions that serve low-income children.

The overarching primary research question that will be answered is:

Can existing effective evidence-based PWMIs be packaged and implemented in clinical sites or community venues other than those from which the PWMI originated, be acceptable to lower-income families, and achieve intended outcomes among low-income children aged 2-12 years with obesity?

Healthy People 2020 and other National Strategic Priorities

This NOFO supports the 2020 Healthy People (29) Nutrition, Weight Status and Physical Activity topic areas.

Public Health Impact

This research opportunity has the potential to address the pressing public health problem of childhood obesity by increasing the availability of evidence based PWMI for millions of at-risk low-income children, especially CHIP and Medicaid eligible children. This NOFO will provide an opportunity for interventions with a solid research base to be packaged and implemented within new organizations. This process contributes to the pediatric obesity field by evaluating the effectiveness of proven interventions in real-world settings (27.K2A framework) resulting in improved public health knowledge of how to bring PWMI interventions to practice. Evidence based packaged PWMIs created from this research can be used by state and federal agencies, community based organizations, healthcare organizations and scaled to a variety of circumstances and payers.

Relevant Work

This NOFO will address the problem of how to manage childhood obesity and will build on lessons learned from previously funded Childhood Obesity Research Demonstration projects (CORD) 1.0 and 2.0 (30. https://www.cdc.gov/obesity/strategies/healthcare/cord1.html), and with relevant capacity-building assistance (CBA) projects with nongovernmental public health components such as the National Association of Community Health Centers (NACHC). This NOFO utilizes the NCCDPHP Knowledge to Action Framework and builds off of work to replicate and disseminate effective programs from other CDC Divisions, such as HIV (31. https://www.cdc.gov/hiv/research/interventionresearch/rep/index.html; 28. Collins 2011), arthritis (32. https://www.cdc.gov/arthritis/interventions/index.htm), and diabetes (33.

https://www.cdc.gov/diabetes/prevention/index.html).

2. Approach

Grantees will be funded for a 5 year period with varying funding levels throughout the project period due to the number and nature of activities anticipated (see objectives/outcomes below). The approach builds on prior childhood obesity research demonstration (CORD) projects in implementing a model for reducing childhood obesity among low-income children with overweight or obesity. The demonstration shall provide support to target children and their families to reduce risk factors through the appropriate use of screening, preventive, and management benefits and ongoing community supports. The demonstration will carry out activities to increase the availability of packaged effective pediatric weight management interventions (PWMI) that can be used by healthcare, community or public health organizations to serve low-income children and their caregivers. To achieve this, researchers/research teams will take the existing evidence based PWMI and create a "package" that supports all required elements for implementing the evidence based intervention in other locations, including all supporting materials in user-friendly formats, implementation manuals, training curricula, technical assistance and evaluation/quality control materials and pilot test them in real world settings. Awardees will conduct a rigorous research study to assess implementation, delivery system and child/family outcomes as they pilot the PWMI materials package in two or more clinical or community organizations. This approach can strengthen local, state and national public health chronic disease prevention and treatment efforts by presenting an opportunity for scientists to translate their proven behavioral interventions into practical materials for more widespread implementation. This NOFO aims to include a diversity of PWMI packages that draw upon effective, innovative models to reduce behavioral risk factors and improve health. For example PWMIs that target different age ranges, such as PWMIs that include: younger children (aged 2 to 5), school aged children or older children; or PWMIs that are targeted to different racial or ethnic groups; or that include different intervention approaches or settings, such as those that are individual, group based, online, or mixed formats.

The PWMIs targeted for this funding announcement **must have a solid and rigorous evidence base**. For example, interventions included in the evidence reviews for the 2010 or 2017 USPSTF Recommendation for childhood obesity, or other similarly rigorous systematic reviews. The successful applicant should provide supporting information in their research plan that demonstrates the PWMI has been: 1) rigorously evaluated such as in the form of a Randomized Control Trial (RCT); 2) meets the USPSTF recommendations for dose and intensity; 3) is family based; 4) includes nutrition and physical activity counseling; and 5) improves BMI in children 2 to 12 years old.

During the 5-year funding period applicants are required to take their evidence-based PWMI intervention and: 1) "package" together all materials necessary to carry out the PWMI in a user-friendly turn-key format; 2) conduct a pilot implementation research study and aid pilot sites in engaging with multisectoral stakeholders to refer children and families to PWMI and help link to community resources for healthy nutrition and physical activity; 3) finalize their PWMI based on data and feedback from the pilot implementation study; and 4) develop a sustainability

and dissemination plan.

This NOFO specifically targets PWMIs that can be implemented by providers and organizations that serve low-income children ages 2 to 12 years affected by childhood obesity, such as children covered CHIP or Medicaid programs. The applicant will need to fully describe plans for creating the "package" of PWMI materials. The package will need to consider multiple components including nutritional content, understanding and responding to hunger and satiety, positive body image development, positive self-esteem development, and learning life skills (such as stress management, communication skills, problem solving and decision making skills), as well as consideration of cultural, family, peer, and developmental issues. The package must include all materials necessary for a new provider/organization to implement the intervention such as an implementation manual, a training curriculum, technical assistance (TA) and evaluation materials.

The applicant will conduct pilot implementation research by identifying and collaborating with at least two additional healthcare, community or public health organizations, that serve low-income children and families aged 2 to 12 as part of their patient population. These two local organizations will use the package of training, technical assistance, evaluation and intervention manual materials in their real-world setting. During the pilot the grantee will collect data on: 1) outcome measures commonly used in implementation research (e.g., acceptability, adoption, appropriateness, cost, and fidelity); 2) delivery system/service outcome measures (e.g., efficiency, effectiveness, timeliness, patient centeredness); and child/family outcome measures to determine if children and families participating in the pilot sites improved health outcomes and BMI through participation in the PWMI (34. Proctor et al, 2011). Rigorous designs for the implementation research study should be used such as those that utilize designs common to the fields of quality improvement, evaluation or implementation research. These designs could involve matched comparison groups, propensity-score matching, instrumental variable methods, regression discontinuity, time series designs, hybrid or other designs. Applicants should not include experimental research designs (i.e., randomized controlled trials [RCT]), as the intention of this NOFO is to implement interventions that have already documented efficacy via RCT. Data analytic plans should be appropriate to the implementation strategy, research design, hypotheses, and data collection measures.

Pilot sites will also document their experiences in recruiting and retaining enrolled children and families to participate in the PWMI and linking children and families to community resources. Finally, the pilot sites will also provide feedback to the research team on the PWMI package of materials.

At the end of the project period CDC aims for grantees to have a packaged program, built on a strong evidence base, that organizations can obtain and that can be widely disseminated for implementation in healthcare, community or public health settings that that includes a strategy for extending program activities. Data generated through the implementation research pilot will assess relevant outcomes from the evidence based PWMI implementation in real world settings,

and will determine how similar the outcomes were to those of previous trials of the PWMI. Over the course of the project period there may be other supplemental opportunities to support enhanced PWMI activities. Examples of such activities include additional package testing, additional site testing, and dissemination.

Objectives/Outcomes

The grant has specified objectives, activities, and outputs/outcomes that are described in detail below. The demonstration project should identify and build upon existing community, regional and state resources, and relationships. The overarching outcome is to increase the availability and number of packaged effective PWMIs that can be used by healthcare, community or public health organizations that serve low-income children. Each year of funding will build on the previous year's activities to reach the NOFO's desired objectives and outcomes.

Objective 1: Develop an intervention package that includes all materials necessary for others to implement the intervention in new places. This includes the following activities:

- package the curriculum, sessions, intervention activities,
- engage with community coalition partners and develop family support and educational materials such as templates to help link families to needed community resources and supports such as food assistance services, healthy lifestyles, or increased access to safe places for physical activity (i.e. after hours physical activity programs and opportunities through schools, parks and recreational services or community based organizations);
- develop training materials and training capacity;

- develop a minimum set of evaluation criteria for PWMI and a way to track key outcomes typically used in implementation research (34. Proctor et al, 2011) such as:
    - implementation outcomes (e.g., acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration/reach and sustainability)
    - delivery/service outcomes (e.g., efficiency, safety, effectiveness, equity, patient/family centeredness, timeliness)
    - child and caregiver outcomes (e.g. acceptability, satisfaction, patient dose received over what period of time, quality of life, obesity-related behaviors, other health outcomes and BMI)

- develop fidelity measures and a way to track program fidelity;
- develop a method to collect information on the cost including cost of the intervention materials, the cost of delivery, and the cost of implementation; and
- in conjunction with pilot sites, obtain all approvals necessary, such as IRB or others, to carry out the pilot research study and develop a plan for recruiting children into the PWMI.

The anticipated outputs from objective 1 include: the package including all supporting materials in user-friendly formats, implementation manuals, training curricula, the provision of technical assistance and an evaluation and cost monitoring system.

Objective 2: Perform a rigorous pilot implementation research study that tests the intervention in at least two new organizations. This includes the following activities:

- provide PWMI materials, community resource referral materials, technical assistance and training to implementing sites;
- provide implementation support activities and aid pilot sites in engaging broad ranging multisectoral stakeholders as necessary;
- monitor outcomes used in the implementation research pilot; and,
- begin sustainability and dissemination planning:
    - determine/test if the PWMI interventions could be mapped to services eligible for reimbursement; and
    - outline a plan to create a system or structure for others to obtain the intervention, including elements such as a dissemination plan, website, fee structure, and/or training system; and
    - develop a strategy for extending program activities

The anticipated outputs and outcomes from objective 2 include: materials and support necessary to carry out the pilot implementation research study in at least two new organizations. Grantees will begin data collection on outcomes used in the implementation pilot and produce a draft sustainability and dissemination plan.

Objective 3: Complete a pilot study and finalize the PWMI package materials and sustainability and dissemination plan. This includes the following activities:

- complete the pilot study and evaluate the pilot study outcomes;
- make edits to the PWMI package based on pilot experience, finalize the package materials, and provide to CDC for review;
- finalize a sustainability and dissemination plan for additional sites to further spread and scale.
    - In collaboration with CDC, determine if there are other potential sites for dissemination.
    - If disseminated to other sites, sustain a system for technical assistance, perform implementation outcome monitoring (such as fidelity, adoption, and penetration/reach), and utilize a system to monitor key processes and outcomes);
- Compile lessons learned and produce an evaluation synthesis report and aggregate program statistics; and
- Present findings in published literature and conferences.

The anticipated outputs and outcomes from Objective 3 include: Completion of the pilot study; a summary of pilot findings; finalized PWMI package; a sustainability and dissemination plan; an evaluation synthesis report; and presentations and publications.

Target Population

The priority population of this NOFO is low income-children ages 2-12 years who are

overweight or have obesity and their families. Applicants should thoroughly describe the populations included in prior trials of their PWMI interventions and the proposed implementation pilot population, including the age range, racial/ethnic mix, income or poverty level, BMI level (or distribution of weight category) and other relevant population characteristics.

Collaboration/Partnerships

The applicant should identify any key stakeholders that are included in this project and how these collaborations/partnerships will allow the applicant to complete the proposed work. Expected collaborations include:

- A collaboration between the applicant institution and other outside entities necessary to complete the proposed work, such as the two pilot site collaborators, is required. The grantee may also collaborate, and form partnerships, with other entities that are necessary to provide evaluation expertise, access to data, or other types of project support. Documentation of partnerships should describe existing working relationships, plans for the proposed collaboration, nature and extent of involvement of the PI, applicant institution, outside entities, and partner agencies, as well as the scope of work for the outside entity. If partnerships are related to obtaining data from another group (e.g., data from electronic medical records), the applicant should document that they will have access to that data.

- Forming a community advisory board consisting of broad stakeholders such as local health professionals/provider agencies; community health workers; community-based organizations; local governments; local educational agencies; the private sector; State or local departments of health; healthcare providers and members of the intervention's intended populations (families with children ages 2 to 12). Key stakeholders should be engaged early and involved throughout the grant period.

- Forming a payer advisory board consisting of stakeholders from entities such as State Medicaid, private payers, State and/or Local Health Agencies, federally qualified health center or primary care association, major health systems or foundations to help understand potential for sustainability and reimbursement of the PWMI.

- Collaborations/partnerships during the project period to enhance awareness and uptake of packaging and pilot work such as : 1) state and/or local departments of health in close geographic proximity during the development of the dissemination and sustainability plans 2) organizations or entities that can support pilot sites in engaging with existing multisector stakeholders in childhood obesity efforts and refer children and families to

the PWMI and to community resources for healthy nutrition and physical activity to increase awareness and collaboration

- Attending bi-weekly or once monthly CDC grantee conference calls and participate in all annual CDC site visits.

Evaluation/Performance Measurement

Applicants must evaluate and document performance during each stage of the PWMI "packaging", implementation pilot and dissemination planning processes. Applicants should describe how they will evaluate the project objectives outlined above. The evaluation plan should include key grant related activities, as appropriate for each objective, such as partnership development, packaging, pilot implementation study development, recruitment, training, process and outcome measurement, data collection, participant retention, data analysis and dissemination.

The applicant is expected to provide a clear description of relevant measures for each objective of the project. Comparison of actual progress to the project aims and objectives is expected to document whether the demonstration project is progressing appropriately, in a timely manner, and whether planning, packaging, research or dissemination activities are of high quality.

Translation Plan

The applicant should outline a preliminary plan describing how the packaged PWMIs and training materials will be made available to providers who want to obtain the packaged materials and training. The plan should also outline the estimated costs associated with implementing the PWMI after the pilot. Applicants should outline a sustainability plan for the PWMI package to support ongoing or future implementations.

OMB/PRA is not expected to apply

References:

1. Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of Obesity Among Adults and Youth: United States, 2015-2016. Atlanta, GA: Centers for Disease Control and Prevention, US Dept of Health and Human Services; 2017.
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Section II. Award Information

Funding Instrument Type: Cooperative Agreement

A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

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

Estimated Total Funding: $12,500,000
The estimated total funding (direct and indirect costs) for the first budget period is $3,750,000, and the estimated total funding (direct and indirect) for the entire project period is $12,500,000 for the project period of 4/1/2019 to 3/31/2024

It is anticipated that award(s) will be made under this CDC-RFA-DP19-002, with an average funding level of $2,500,000 per grantee over the project period.

Awards issued under this FOA are contingent on the availability of funds and submission of 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.

Anticipated Number of Awards: 5

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

Award Ceiling: $750,000 Per Budget Period
Award Floor: $200,000 Per Budget Period
Total Period of Performance Length: 5 year(s)

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

HHS/CDC grants policies as described in the HHS Grants Policy Statement (http://www.hhs.gov/ sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:	Others (see text field entitled "Additional Information on Eligibility" for clarification)

Additional Eligibility Category:

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

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

For this announcement, applicants may include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

As determined by legislative language, eligible applicants include the following:

A city, county, or Indian tribe.

A local or tribal educational agency.

An accredited university, college, or community college.

A Federally-qualified health center.

A local health department.

A health care provider.*

A community-based organization.**

*A health care provider provides health care or represents a health care system or group of health care professionals that provides care to individuals.

**A *Community-based organization (CBO)* is a public or private non-profit organization (including a church or religious organization) that is representative of a community or a significant segment of a community, and is engaged in meeting human, educational, environmental, or public safety community needs.

4. Justification for Less than Maximum Competition

Statutory Authority and Congressional language specifically identifies eligibility entities listed in Section III (1).

5. Responsiveness

Applications under this program must meet the requirements set out under (1) Eligible

Applicants and (3) Special Eligibility requirements. These requirements are the minimum necessary in order for an application to be responsive and sent forward for scientific peer review. If your application is incomplete or non-responsive to the eligibility requirements in these sections, it will not enter into the review process.

6. Required Registrations

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

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https:// eportal.nspa.nato. int/ AC135Public/ Docs/ US%20Instructions%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/.
- Grants.gov
- eRA Commons

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

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

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

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal

Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number. Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/index.html.
If an award is granted, the recipient organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the recipient organization.

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

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

9. Cost Sharing

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

10. Number of Applications

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

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

Section IV. Application and Submission Information

1. Address to Request Application Package

In order to use ASSIST, applicants must visit https://public.era.nih.gov/assist where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process.
If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via:

- E-mail: http://grants.nih.gov/support/index.html
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552. The NIH eRA Service desk is available Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf, except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.
When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

3. Letter of Intent

Due Date for Letter of Intent: **09/24/2018**

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

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

- Name of the Applicant
- Descriptive title of proposed research
- The name of the Pediatric Weight Management Intervention (PWMI) proposed for packaging
- Name, address, and telephone number of the PD(s)/PI(s)
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

The letter of intent should be sent to:
Natalie Darling

Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30342
Telephone: (770)-488-5740
Email: ndh6@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf and https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).
Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. **Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the NOFO.
2. **Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. **Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and time line.
4. **Progress Report Publication List** (for Continuation ONLY)

Other Research Plan Sections

5. **Vertebrate Animals**
6. **Select Agent Research**
7. **Multiple PD/PI Leadership Plan.**
8. **Consortium/Contractual Arrangements**

9. Letters of Support
10. Resource Sharing Plan(s)
11. Authentication of Key Biological and/or Chemical Resources
12. Appendix

All instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf must be followed along with any additional instructions provided in the NOFO.
Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.
The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:
• Descriptions of the data to be produced in the proposed project
• How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use
• Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified
Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

RESEARCH PLAN
The applicant's research plan should address activities that will be conducted over the entire project period. NOTE: that the Research Strategy is divided into three parts: 1) Significance, 2) Innovation, and 3) Approach. The research plan should provide information on the following topics and address activities that will be conducted over the project period:

Introduction and Description of the PWMI

Applicants should describe:
1. The PWMI, include a brief history of how the PWMI was created and the underlying behavioral theory which underpin intervention activities. Demonstrate that the proposed PWMI has:

- Been tested in children within the range of 2 to 12 years of age. The PWMI is not required to include all ages within this range but must include the target age range of children between 2 and 12 years of age.
- Been rigorously evaluated through one or more randomized control trials (RCT) that had an a priori outcome of improvement in the BMI of children between the ages of 2 and 12 and provide documentation,such as a citation from the peer reviewed publication,

showing efficacy. This also includes a summary of the original target population.

2. The PWMI components, curriculum (if applicable) and intervention strategies of the PWMI. The applicant needs to outline the RCT tested core components of the program or intervention that must be implemented with fidelity (e.g., nutrition education, skill building) as well as elements that may be adapted for various contexts and conditions (e.g., operating hours, delivery team makeup in clinical versus community setting).
3. The format of the intervention (group based, individual based, virtual, phone/text support, mixed-format etc.) and setting that the intervention can be carried out in.
4. The intervention curriculum as it relates to key behaviors (e.g., nutrition literacy, snacking, healthy beverages, portion size, label reading, eating for comfort, parenting styles, physical activity, stress management, sleep) and plan for referral to community resources.
5. The number of sessions, length of the sessions, and the attrition rates found in previous studies. The applicant should demonstrate that the program follows the USPSTF recommendation of moderate (>25-75 hours) or high (75+ hours) intensity and includes both nutrition and physical activity counseling.
6. The main process and outcomes used for previous studies/evaluations of the PWMI.
7. If/how the intervention includes developmentally appropriate materials and activities aimed at behavior change in children and families.
8. The age range of children this intervention targets and who from the family needs to participate.

Applicants must describe the staffing, facilities and approach required to deliver the intervention:
1. Describe the staff/interventionists required to carry out the PWMI activities. This could be interventionists such as a physician, physician's assistant, nurse, nurse practitioner, behavioral interventionists, subspecialists, Community Health Workers (CHWs), care coordinators or others.
2. Describe the training of the staff/interventionists necessary to be able to deliver the PWMI.
3. Describe the physical space needed to carry out the intervention.

Applicants must describe how children and families have been enrolled in the past and if the intervention can be delivered reliably in practice.

1. Discuss whether the intervention has been implemented/scaled to other sites. If it has been spread to other places, provide data such as the number of places who have acquired the PWMI, the number of participants that completed the program, and costs associated with acquiring and implementing the intervention.
2. Describe if there are requirements for a certain number of children and families to participate in the program. Describe what method will be used to enroll sufficient amounts of low-income children and families into the program (e.g., through BMI reports, rolling recruitment, a hub and spoke model).
3. Describe previous efforts or incentives to encourage participant retention in the family-centered PWMI.
4. Describe the how the PWMI can be implemented in a new organization.

Packaging of the PWMI:
Applicants must describe how all materials necessary to implement the PWMI will be "packaged" together in a user-friendly turn-key format. The approach for the development of the PWMI intervention package should include:

1. A description of the plan to package the PWMI intervention materials, intervention strategies, training curricula, TA manual and training necessary to carry out the PWMI.
2. A description of the applicant's staffing and expertise to accomplish packaging the PWMI as well as a timeline for the packaging process. Expertise can included but is not limited to expertise in curricula and package development, health education and technical writing.
3. A description of plans to form multisectoral collaborations and an advisory group that includes involvement of a broad range of stakeholders such as representatives from local community based organizations, health care providers, and local provider agencies and members of the intervention's intended populations (families with children ages 2 to 12) to provide input on the packaging of materials and acceptability of referrals to community resources.

Implementation Research Study:

For this implementation research project, applications that include experimental designs such as RCT should NOT be included in this NOFO, as the intention is to implement interventions that have already documented efficacy via RCT. Applicants should describe the following:
1. The plan to recruit two or more healthcare or community organizations that are located in communities that serve low-income children and families to pilot the packaged PWMI materials. Describe the agencies/clinics/venues that will pilot the PWMI. Provide a letter of intent from at least two organizations that will participate in the implementation pilot study.
2. The pilot implementation research design. Rigorous designs for the implementation research study should be used such as those that utilize designs common to the fields of quality improvement, evaluation or implementation research. These designs could involve matched comparison groups, propensity-score matching, instrumental variable methods, regression discontinuity, time series designs, hybrid or other non-RCT designs.
3. Plans for recruitment, enrollment, completion, boosting/maintaining children and families sufficient for proposed study design. Prior studies indicate that very large pools of eligible children may be required to recruit and enroll sufficient numbers of children in PWMIs (documenting assumed attrition, for example, 5-20% of eligible children recruited, 80% of children recruited enroll, 50% of children enroll complete).
4. Plans for engagement with community partners to aid in the referral of target children and families to the PWMI and community resources.
5. Plans for measurement of key outcomes including, implementation research outcomes, system/service delivery outcomes, and child and family outcomes.
6. Data analytic methods.
7. Plans for data collection, data security, and data management including how issues of privacy and confidentiality will be addressed.
8. Measures to assess adherence to program fidelity.
9. The approach the applicant will use to determine if the PWMI package, when implemented in other locations, is:
    a. Acceptable to implementing staff and children and families who participate

b. Effective in aiding children and families improve health and weight related outcomes.
10. Plans to provide technical assistance and ongoing quality improvement to ensure adequate implementation in pilot sites.
11. Plans to capture cost data to understand how much these programs cost per child/family and the initial and ongoing costs associated with implementing a PWMI in a new entity or organization. Cost collection plans should consider costs directly paid for by the program as well as in-kind services or resources provided by program staff and stakeholders as well as partners. Additionally, describe any reimbursement for delivery of the PWMI that will occur and any potentially sustainable fiscal models that have been developed or utilized with this PWMI.
12. Discussion of how grantee will compile lessons learned.

Dissemination Plan:
Applicant should describe a plan for how, following packaging and the pilot study, the PWMI (and the curriculum, training and technical assistance necessary to carry out the program) will be promoted and potentially disseminated to a wider scale audience such as healthcare, community, or public health entities who wish to acquire the packaged PWMI. This could include a:
1. Description any marketing materials or efforts that may be part of promoting the PWMI; and
2. Description of a plan for sustainability, which should outline a potential fee structure and dissemination plan and a strategy for extending program activities.

Project Management and staffing

The applicant should describe:
1. A staffing plan that defines the roles, responsibilities and qualifications of the team and expected contributions of key/collaborative partners;
2. A detailed timeline including realistic and measurable milestones for project objectives and activities and include a budget plan that is linked to objectives and activities;
3. Plans for producing reports: This includes interim progress reports, a final report, as well as technical reports, professional presentations, and potential publications that may be produced.

6. Appendix

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

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 25 pages.

Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 35 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.
CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes.
Organizations must submit applications using the ASSIST web-based application preparation and submission process.
ASSIST will validate applications before submission. If the system detects errors, then the applicant must correct errors before their application can be submitted.
Applicants are responsible for viewing their application in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application resubmitted in ASSIST.
Applicants are able to access, view, and track the status of their applications in the eRA Commons.
Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at https://era.nih.gov/files/ASSIST_user_guide.pdf.
Note: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).
Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on federal holidays)

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

https://www.grants.gov/web/grants/support.html
support@grants.gov
Hours: 24 hours a day, 7 days a week (closed on federal holidays)
If the applicant encounters problems that prevent the ability to submit an application which cannot be resolved by Grants.gov or NIH eRA Service Desks, then applicants must contact CDC Technical Information Management Section (TIMS) at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date. Therefore, it is important that applicants complete the application submission process well in advance of the due date time.
After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor agency has confirmed receipt of the application.

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

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

    a. If the status states "**rejected**", do #2a or #2b

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

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

Due Date for Applications: **10/24/2018**

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

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 75, terms and conditions, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.
In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly

prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).
For more information on expanded authority and pre-award costs, go to: https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards. Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.
Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).
Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html for revised AR-25.

Applicants are advised that any activities involving standard information collection (i.e., surveys, questionnaires, data requests, etc.) from 10 or more non-federal individual/entities are subject to Paperwork Reduction Act (PRA) requirements and may require the CDC to coordinate an OMB/PRA approval request).

Through the research efforts of this NOFO recipients will work to improve community, clinical or public health models to reduce childhood obesity. Recipients will use the funds made available under this NOFO to-

- carry out community-based activities related to reducing childhood obesity;
- carry out educational, counseling, promotional, and training activities through the local health care delivery systems

12. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR

75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.
CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS.

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

Duplication of Efforts
Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. Report Submission: The applicant must upload the report under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

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

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

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

Important reminders:
All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.
The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.
If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

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

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

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

Section V. Application Review Information

1. Criteria

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

Overall Impact
Reviewers will provide an overall impact/priority score to reflect their assessment of the

likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

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

Significance

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

Evidence that the intervention is effective:
• Does the applicant provide documentation of how the PWMI was created and the underlying behavioral theory which underpins intervention activities?

• Does the applicant demonstrate that the proposed PWMI has:

- Been tested in children within the range of 2 to 12 years of age. The PWMI is not required to include all ages within this range but must include the target age range of children between 2 and 12 years of age.
- Been rigorously evaluated through one or more randomized control trials (RCT) that had an a priori outcome of improvement in the BMI of children between the ages of 2 and 12 and
- Have evidence in the form of 1 or more peer reviewed publications documenting that it is effective in improving the BMI outcome in children ages 2-12 years?

• In addition to the initial RCT, has the intervention been implemented/scaled to other sites? If it has been spread to other places, were data provided on the number of places that have acquired the PWMI and the number of participants that were recruited and completed the program?

Evidence that the intervention is of high quality:
• Is the proposed intervention consistent with the USPSTF grade B recommendations in that it:
Includes comprehensive, intensive behavioral interventions;
- Demonstrates that the intervention's dose (number of sessions, length of sessions, duration, total hours) and intensity (time period) is moderate (>25-75 hours) or high (75+ hours) over 2-12 months
- Includes both nutrition and physical activity counseling and family-centered behavior modification techniques?
• Is there adequate description of the format of treatment services, including session type(s) (group versus 1:1), mode (in person, virtual, mixed-format), regularity of sessions (e.g.,

weekly, twice weekly, once monthly), and diversity of setting(s) (clinics, community venues) where the PWMI can be delivered?
• Does the applicant describe the process and outcome measures used in previous research studies or evaluations?
• Has the program demonstrated acceptability for low-income families and for clinical or community service provider staff who will carry out the PWMI (e.g., office manager, physicians, nurses, medical assistants, behavioral health specialists, CHWs or other interventionists)?

Evidence that the program has potential for sustainability and scalability:
• How feasible is implementation of the proposed PWMI in real world settings?
• Is the PWMI scalable? Does the application describe how the results from the research will be disseminated and ultimately scaled to be used by service providers who serve low-income children?
• Does the applicant describe any reimbursement for delivery of the PWMI that is occurring or any potentially sustainable fiscal models that have been developed or utilized with this PWMI?

Investigator(s)

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

• Do they adequately describe how the proposed research team will support and collaborate with the pilot site providers who will carry out the intervention?
• Does the research team include staff with the skills and expertise needed to develop a user-friendly package of materials including skills in curricula and package development, health education, and strong writer-editor skills?
• How much time do the PI and other key staff dedicate to the project? Does this seem adequate to carry out the work?
• Has the applicant described plans to form collaborations and advisory group that include a broad range of multisectoral stakeholders and how these will inform the packaging process, community referral strategy and overall project?
• Does the applicant's staffing, expertise, and timeline to accomplish packaging the PWMI, implementing a pilot study at two or more organizations, and finalizing the PWMI seem appropriate for the NOFO's objectives and time period?

Innovation

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

- Is the proposed research innovative and yet offer reasonable potential for concrete

applications of interest and value to CDC and other state and federal partners? Has the grantee described how lessons learned that will be compiled and potentially added to the PWMI package for future dissemination?

- Does the approach for creating a sustainability and dissemination plan seem appropriate per utilization of reimbursable services not solely dependent on grant funds? Does the applicant outline or describe a strategy for extending program activities?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Is there evidence that the applicant has access to the intervention materials? If the PWMI was originally developed by someone else, does the applicant have permission from the developer to use the PWMI intervention materials?

Is there evidence that the applicant will successfully meet each of the 3 main grant objectives

Objective 1 Packaging:
• Have they described how all materials necessary to implement the PWMI will be "packaged" together in a user-friendly, turn-key format?

Objective 2 Performing a rigorous pilot:
• Does the applicant have a solid plan to recruit two or more healthcare or community organizations to pilot the packaged PWMI materials? Does the applicant describe venues who reach low-income eligible vulnerable children which will pilot the PWMI and provide a letter of intent from these organizations? Has the applicant described how children will be identified and how referrals will be made to the program in the pilot, such that the PWMI may be able to enroll sufficient amounts of low-income children and families into the program (e.g., through electronic health record BMI reports/registries, and existing network of primary care providers rolling recruitment, a hub and spoke model)?
• Does the pilot implementation research study use rigorous methods including appropriate power to evaluate the PWMI implementation and discuss how data will be collected and managed? Are implementation outcomes on several levels including the program level (such as acceptability, appropriateness, cost, feasibility, fidelity, reach) the service/delivery level (such as efficiency, safety, family centeredness, effectiveness, provider satisfaction) and at the child/family level (such as satisfaction, quality of life, health and weight outcomes) included?
• Does the applicant describe the training and resources necessary for the pilot sites to be able to deliver the intervention?
• Does the applicant outline plans to provide technical assistance and ongoing quality improvement to ensure adequate implementation in pilot sites?

Objective 3 Finalizing the PWMI, and creating a dissemination and sustainability plan:
• Does the applicant adequately describe how packaging and pilot research findings will inform the future dissemination and sustainability of the package?

• Does the applicant describe a plan to capture cost of implementation, develop a potential fee structure, and a way to contain costs to make it available at a reasonable price to other organizations?

Evaluation:
• Does the application outline in their evaluation plan how the objectives for each funding year will be met?

Environment

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

• Does the project utilize critical partnerships or collaborations to accomplish the NOFO intent and objectives?

• Does the project support key stakeholder involvement throughout the design, research, and sustainability planning process?

• Does the applicant have access to qualified personnel who are well-suited to accomplish the project goals and objectives?

2. Additional Review Criteria

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

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

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

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

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

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VASchecklist.pdf).

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

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

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

3. Additional Review Considerations

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

impact/priority score.

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

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

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

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

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

• Type of data to be produced in the proposed project;
• Mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights);
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified.

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

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html
The budget can include both direct costs and indirect costs as allowed.
Indirect costs could include the cost of collecting, managing, sharing and preserving data.
Indirect costs on grants awarded to foreign organizations and foreign public entities and

performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.
Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.
If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

4. Review and Selection Process

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

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

- Will receive a written critique.

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

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

• Diversity of PWMI packages. Examples of diversity of PWMI packages could include:
- PWMIs that include different age ranges, such as PWMIs that include younger children (aged 2 to 5), or school aged children or older children;
- PWMIs that are targeted to different racial or ethnic groups; and/or
- PWMIs that include different intervention approaches, such as those that are individual, group based, online, or mixed formats.
• Diversity of pilot sites by geography (e.g., pilot sites from different grantees should be diverse and not within the same municipality).

In making awards, in alignment with congressional intent, priority shall be given to eligible entities-
• that provide non-Federal contributions, either in cash or in-kind, to the costs of funding activities under the grants;
• that develop comprehensive plans that include a strategy for extending program activities developed under grants in the years following funding
• that submit plans that exhibit multisectoral, cooperative conduct that includes the involvement of a broad range of stakeholders, including-
(i) community-based organizations;
(ii) local governments;
(iii) local educational agencies;
(iv) the private sector;
(v) State or local departments of health;
(vi) accredited colleges, universities, and community colleges;
(vii) health care providers;
(viii) State and local departments of transportation and city planning.

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

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

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

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

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

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

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

2. CDC Administrative Requirements

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

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

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements

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

AR-8: Public Health System Reporting Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

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

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

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

AR-31: Research Definition

AR-32: Appropriations Act, General Provisions

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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

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

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

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

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

authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

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

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

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

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

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

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

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

The AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.
Certificates of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at: https://www.cdc.gov/grants/additionalrequirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

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

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

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 http://intranet.cdc.gov/od/oads/spa/dma/index.html

The PD(s)/PI(s) will have the primary responsibility for:
• Designing, conducting and implementing the project research plan to address the described objectives of this cooperative agreement.
• Guiding and coordinating the work of the project team and ensuring effective linkage, communication and accountability.
• Sharing evaluation information with the CDC.
• Obtaining the appropriate Institutional Review Board approvals for research involving human subjects.
• Participating in CDC-sponsored meetings as scheduled by CDC.
• Conducting analyses, interpreting results, and disseminating findings in peer-reviewed journals, technical reports, research and policy briefs, presentations at professional and scientific conference and policy forums, as appropriate, and contributing scientific findings to appropriate Web sites or and policy forums, as appropriate, and contributing scientific findings to appropriate Web sites or other channels for sharing findings.
• The Principal Investigator will attend at least one in-person meeting per year and conference calls regularly, as scheduled in consultation with CDC.
• Other members of the research team will participate in appropriate sub-committees and CDC-sponsored meetings.
• Ensure adequate management, staffing, oversight, and mentoring of research team members in support of the project activities.

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

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:
• Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Nonresearch Data Management and Access http://intranet.cdc.gov/od/oads/spa/dma/index.html

There are two CDC scientific roles – the Scientific Collaborator (SC) and the Scientific Program Official (SPO).
In this cooperative agreement NCCDPHP SC will provide technical assistance for scientific and programmatic aspects during the conduct of the project through technical assistance, advice, and coordination. NCCDPHP SC and additional scientific consultants will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:
• At the awardees request, provide expertise and guidance on the packaging and implementation approaches;
• At the awardees request, provide expertise related to data collection methods, outcome measures, and evaluation plan; and
• Provide technical assistance and foster collaboration between all awardees during the project period.

Additionally, an HHS/CDC Project Officer or other HHS/CDC staff will provide day-to-day programmatic, administrative, and fiscal management in support of the project as defined above.

Additionally, an HHS/CDC agency Program Official will be responsible for the normal scientific and programmatic stewardship of the award. The SPO will be:
• Named in the Notice of Grant Award (NGA) as the Program Official to provide oversight and assure overall scientific and programmatic stewardship of the award;
• Monitor performance against approved project objectives; and
• Assure assessment of the public health impact of the research conducted under this funding opportunity announcement and promote translation of promising practices, programs, interventions, and other results from the research.

Areas of Joint Responsibility include:
A group may be formed after grantees are awarded and made up of a Principal Investigator from each funded awardee, and key CDC staff such as the SC. This Committee will work together on common issues of funded projects. It is expected that awardees communicate and collaborate with other funded recipients on project-related issues.

5. Reporting

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

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

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

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:
1) Information on executive compensation when not already reported through the SAM Registration; and
2) Similar information on all sub-awards/ subcontracts/ consortiums over $25,000. It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

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

1. **Yearly Non-Competing Grant Progress Report**, is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

2. **Annual Federal Financial Report (FFR) SF 425** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends**.

3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the period of performance**.

B. Content of Reports

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

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

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

- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences,

including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. Questions to consider in preparing this section include:

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

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

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

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

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

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made

at this stage in the project, simply indicate “Not applicable: No publications or presentations have been made."

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

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

- Additional Reporting Requirements:

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

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.
Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.
The due date for final FFRs will continue to be 90 days after the Period of Performance end date.
Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning

the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://grants.nih.gov/support/index.html

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

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

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

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

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

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

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

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

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

Section VII. Agency Contacts

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

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

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

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

Scientific/Research Contact:
Natalie Darling
Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30342
Telephone: (770)-488-5740
Email: ndh6@cdc.gov@cdc.gov

Peer Review Contact:

Jaya Raman, Ph.D.
Scientific Review Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30342
Telephone: (770)-488-6511
Email: kva5@cdc.gov

Financial/Grants Management Contact(s):
Monique Tatum
Grants Management Specialist/Office of Financial Resources(OFR),

Office of Grant Services (OGS),
Telephone: 770-488-2617
Email:Mtatum@cdc.gov

Section VIII. Other Information

Other CDC Notices of Funding Opportunities can be found at www.grants.gov.
All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

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

Questions from Potential Applicants and CDC Responses for NOFO DP19-002 "Packaging and Spreading Proven Pediatric Weight Management Interventions for Use by Low-Income Families"

Question 1:

Q1A. Our organization is interested in applying for the CDC Demonstration Project-Packaging and Spreading Proven Pediatric Weight Management Interventions (RFA-DP-19-002). Are only previously funded childhood obesity research demonstrations projects eligible to apply?

Q1B. In addition, as a County Hospital System are we eligible to apply?

Response to Q1A: This is a new and open competition Notice Of Funding Opportunity (NOFO). All eligible entities may apply.

Response to Q1B: CDC looks at the eligibility of the applying institution/organization in determining if an application is eligible. An applicant must meet at least one of the Special Eligibility Requirements outlined in the NOFO to be eligible for application. Refer to Section III. Eligibility Information; 3. Special Eligibility Requirements.

A health care provider provides health care or represents a healthcare system or group of healthcare professionals that provides care to individuals.

We will amend the NOFO prior to the application due date to reflect the definition of health care provider.

Question 2:

Q2A. The RFA states that the pediatric weight management intervention (PWMI) should be evaluated for outcomes, quality of life, and satisfaction. We are assuming that 'outcomes' pertains to a measure of obesity status (e.g., BMI z-score, etc.), as well as diet and physical activity. Should the 'outcomes' be the same or similar as the outcomes in the original PWMI trial?

Q2B. For the RFA, does the newly packaged and delivered PWMI need to compared against the original intervention (the one tested in the RCT) as part of the pilot study?

Q2C. Since the RFA calls for a pilot study, we are assuming that we can use different study designs as compared to a fully powered RCT. Is that correct?

Response to Q2A: Per page 9 of 50 in the NOFO, outcomes measures are defined as follows.

"During the pilot the grantee will collect data on: 1) outcome measures commonly used in implementation research (e.g., acceptability, adoption, appropriateness, cost, and fidelity); 2) delivery system/service outcome measures (e.g., efficiency, effectiveness, timeliness, patient centeredness); and child/family outcome measures to determine if children and families participating in the pilot sites improved health outcomes and BMI through participation in the PWMI". Also from page 9, "Data generated through the implementation research pilot will assess **relevant** outcomes from the evidence based PWMI implementation in real world settings, and will determine how similar the outcomes were to those of previous trials of the PWMI." Please note word "relevant". Not all RCT outcome measures will be relevant for the pilot implementation, but the "relevant" measures should be comparable from the pilot to the original RCT.

Response to Q2B: Please see page 9 of 50: "Data generated through the implementation research pilot will assess relevant outcomes from the evidence based PWMI implementation in real world settings, and will determine how similar the outcomes were to those of previous trials of the PWMI."

Response to Q2C: Yes, that is correct. Per page 9 of 50, information on study designs are outlined as follows:

"Rigorous designs for the implementation research study should be used such as those that utilize designs common to the fields of quality improvement, evaluation or implementation research. These designs could involve matched comparison groups, propensity-score matching, instrumental variable methods, regression discontinuity, time series designs, hybrid or other

designs. Applicants should not include experimental research designs (i.e., randomized controlled trials [RCT]), as the intention of this NOFO is to implement interventions that have already documented efficacy via RCT."

Question 3:

My colleagues and I have been working testing different childhood obesity interventions that might fit in rural and micropolitan settings—some of our ideas seem to fit really well with the funding announcement for pediatric weight management, but we have a few questions to see if we are on the right track.

Q3A. First, the intervention we are testing is an adaptation of Epstein's traffic light program that has a bunch of efficacy testing and we have local program data that shows kids are reducing their BMI z-scores by roughly the same amount as Epstein was finding in his trials—but no RCT data on the local program. In my view the program is evidence-based and would fit the call. Is that your take too?

Q3B. Second, doing this in rural and micropolitan communities means that the two (or more) sites that we select will likely recruit a smaller number of families (i.e., 20-30 would be a big cohort). Is there a minimum 'n' you are looking for on the demonstration phase of the award?

Q3C. Third, Traffic Light doesn't include self-esteem or body image content explicitly. Does the proposed program have to cover all of the topics listed in the call for proposals? Or is highlighting that it is an evidence-based program enough?

Response to Q3A:

CDC cannot comment on specific approaches, programs, or designs; however, applicants are encouraged to carefully review the goals and objectives and desired outcomes described in the NOFO.

However, applicants will be evaluated during the merit review process on how well the PWMI meets the listed criteria for a solid and rigorous evidence base. The applicant should provide information to address these criteria in the research plan. The criteria are that PWMI has been: 1) rigorously evaluated such as in the form of a Randomized Control Trial l (RCT); 2) meets the USPSTF recommendations for dose and intensity; 3) is family based; 4) includes nutrition and physical activity counseling; and 5) improves BMI in children 2 to 12 years old." (See pages 8, 22 and 29-31 of 50 in the NOFO for more information on the approach, research plan and evaluation criteria).

Adaptations to the RCT-tested interventions/PWMI to improve efficacy, implementation or adoption may have occurred; if so, the applicant should describe these adaptations, and how these adaptations have been evaluated to ensure efficacy.

Response to Q3B:

The NOFO does not address a specific required sample size. Please see page 9 of 50, "Rigorous designs for the implementation research study should be used such as those that utilize designs common to the fields of quality improvement, evaluation or implementation research."

Response to Q3C:

The components, content, topics, and/or curriculum that make up the PWMI are at the discretion of the PI.

Question 4: I'm reaching on with a question around the recent funding opportunity that was announced. We are excited about the opportunity to potentially apply for funding we just want to ensure that our program meets the criteria.

We understand that one of the requirements for the program is that it has been rigorously evaluated (i.e. RCT study design). Our program has been tested in a RCT with a control group of the program content only and an experimental group with the program content along with a game console (ie. Xbox) with two active games. While this RCT doesn't have a true control group in the sense that they didn't compare our program to a group that didn't receive the program (or current best practice) we are hoping that this study would meet the criteria. I have attached the publication for additional information. Other publications have evaluated the program to determine feasibility with a single arm pre-post test design over 6 months along with a study comparing facilitator characteristics.

Response to Q4:

CDC cannot comment on specific approaches, programs, or designs; however, applicants are encouraged to carefully review the goals and objectives and desired outcomes described in the NOFO.

However, applicants will be evaluated during the merit review process on how well the PWMI meets the listed criteria for a solid and rigorous evidence base. The applicant should provide information to address these criteria in the research plan. The criteria are that PWMI has been: 1) rigorously evaluated such as in the form of a Randomized Control Trial l (RCT); 2) meets the USPSTF recommendations for dose and intensity; 3) is family based; 4) includes nutrition and physical activity counseling; and 5) improves BMI in children 2 to 12 years old." (See pages 8, 22 and 29-31 of 50 in the NOFO for more information on the approach, research plan and evaluation criteria).

Adaptations to the RCT-tested interventions/PWMI to improve efficacy, implementation or adoption may have occurred; if so, the applicant should describe these adaptations, and how these adaptations have been evaluated to ensure efficacy.

Question 5:

Eat Smart Move More [name of state] is a statewide nonprofit whose mission is to make the

healthy choice the easy choice. Working in 4 focus areas including Youth Engagement, Advocacy, Community Action and Consumer Awareness, ESMM engages in a multifaceted approach to improving access to healthy foods and places to be active, including advocating at the state and local levels and training and equipping community coalitions to pursue policy, systems, and environmental changes in their communities. ESMM approaches grassroots work through a network of local coalitions around the state. Today there are 29 coalitions covering 31 of [name of state] 46 counties.

We are interested in applying for or being a partner on the above mentioned (in subject) grant. Can you please define what a community organization would be? Would ESMM quality as a community organization? We have relationships with FQHCs and dietitians across the state that implement weight management programs.

Additionally, we are interested in including a youth leadership program into the submission to train young people associated with the PWMI to be advocates for healthier lifestyles within low-income communities. Is this something that would be allowed to be included in the application?

Response to Q5:

We use the following definition for a community based organization:

Community-based organization (CBO): public or private non-profit organization (including a church or religious organization) that is representative of a community or a significant segment of a community, and is engaged in meeting human, educational, environmental, or public safety community needs.

CDC cannot comment on specific approaches, programs, or designs; however, applicants are encouraged to carefully review the goals and objectives and desired outcomes described in the NOFO.

Question 6:

We have a question regarding the requirements for evidence supporting PWMIs to be packaged and tested. We have a technical question regarding the eligibility of our intervention based on criteria #1.

Would the [name of] program meet the CDC's evidence criteria, without another RCT after adding intensity to an effective intervention?

Response to Q6:

CDC cannot comment on specific approaches, programs, or designs; however, applicants are

encouraged to carefully review the goals and objectives and desired outcomes described in the NOFO.

Applicants will be evaluated during the merit review process on how well the PWMI meets the listed criteria for a solid and rigorous evidence base. The applicant should provide information to address these criteria in the research plan. The criteria are that PWMI has been: 1) rigorously evaluated such as in the form of a Randomized Control Trial l (RCT); 2) meets the USPSTF recommendations for dose and intensity; 3) is family based; 4) includes nutrition and physical activity counseling; and 5) improves BMI in children 2 to 12 years old." (See pages 8, 22 and 29-31 of 50 in the NOFO for more information on the approach, research plan and evaluation criteria).

Adaptations to the RCT-tested interventions/PWMI to improve efficacy, implementation or adoption may have occurred; if so, the applicant should describe these adaptations, and how these adaptations have been evaluated to ensure efficacy.

Question 7: We are hoping to apply for this RFA and we were wondering what format you are looking for the packages to contain and in what format? I assume curriculum, staffing for the package content and are you thinking websites, apps or written format for the packages?

Response to Q7:

The format and modality of the package of the PWMI supporting materials are up to the discretion of the PI. Please see page 10 of 50, "The anticipated outputs from objective 1 include: the package including all supporting materials in user-friendly formats"

Question 8: PWMI are complex multifaceted interventions composed of multiple components. When we look in the literature we find some component activities that are shown to be evidence based, and we have incorporated those into our PWMI. But we don't find evidence bases for the full complement of activities for the low income school based population. How do we justify proposing an evidence based PWMI that doesn't have evidence for all of its components?

Response to Q8:

CDC cannot comment on specific approaches, programs, or designs; however, applicants are encouraged to carefully review the goals and objectives and desired outcomes described in the NOFO.

Applicants will be evaluated during the merit review process on how well the PWMI meets the listed criteria for a solid and rigorous evidence base. The applicant should provide information to address these criteria in the research plan. The criteria are that PWMI has been: 1) rigorously evaluated such as in the form of a Randomized Control Trial l (RCT); 2) meets the USPSTF recommendations for dose and intensity; 3) is family based; 4) includes nutrition and physical activity counseling; and 5) improves BMI in children 2 to 12 years old." (See pages 8, 22 and 29-31 of 50 in the NOFO for more information on the approach, research plan and evaluation criteria).

Question 9:

Q9A. The NOFO talks about implementing in 2 organizations. I was wondering whether or not 2 different FQHCs would count as 2 separate organizations. As you can guess, we have many in [name of city] County and they do not all work together. I just wanted to get a sense from you whether or not this is ok, or do they have to be 2 different types of organizations? Like a FQHC or another health system?

Q9B. The NOFO also talks a lot about implementing the mod/high intensity program (>26 hrs). We implement that version, but also have a Guided Self-Help (GSH) version which is 6-8 hrs in intensity. Is it ok to design this like a QI study and start off with the traditional group, but modify to GSH in some settings depending on the feedback we get?

Response to Q9A:

Please see page 9 of 50, "The applicant will conduct pilot implementation research by identifying and collaborating with at least two additional healthcare, community or public health organizations, that serve low-income children and families aged 2 to 12 as part of their patient population. These two local organizations will use the package of training, technical assistance, evaluation and intervention manual materials in their real-world setting."

The NOFO does not state that they have to be different types of organizations.

Response to Q9B:

CDC cannot comment on specific approaches, programs, or designs; however, applicants are encouraged to carefully review the goals and objectives and desired outcomes described in the NOFO.

Applicants will be evaluated during the merit review process on how well the applicant meets the listed criteria in the evaluation section on pages 29-33.

Question 10:

Q10A. Is there a threshold for low income that we should use to define eligible pilot sites?

Q10B. What is the expected size/scale of pilot sites? i.e. would an entire medical system need to be used as a pilot site or would 2-3 clinics be sufficient?

Q10C. How should the pilot sites be related? i.e. should one be a healthcare setting and the other a community organization or can two healthcare setting in different geographic areas be used?

Q10D. Can the packaging of the materials include the development of web-based trainings or apps?

Q10E. Is the sponsor interested in components that would facilitate dissemination in certain settings (e.g. changes in EHR for healthcare settings)?

Response to Q10A: The NOFO did not specify a threshold for identifying low income populations. See page 8 of 50 in the NOFO that states, "This NOFO specifically targets PWMIs that can be implemented by providers and organizations that serve low-income children ages 2 to 12 years affected by childhood obesity, such as children covered CHIP or Medicaid programs." It is up to the discretion of the PI to determine how to specify low income eligibility.

Response to Q10B and 10C: The size, type and/or location of the pilot sites are up to the discretion of the PI. The NOFO requires a minimum of 2 pilot sites, but additional pilot sites would also be acceptable. The NOFO does not specify that they need to be different types of organizations. Please see page 9 of 50, "The applicant will conduct pilot implementation research by identifying and collaborating with at least two additional healthcare, community or public health organizations, that serve low-income children and families aged 2 to 12 as part of their patient population. These two local organizations will use the package of training, technical assistance, evaluation and intervention manual materials in their real-world setting."

Response to Q10D: The format and modality of the package of the PWMI supporting materials are up to the discretion of the PI. Please see page 10 of 50, "The anticipated outputs from objective 1 include: the package including all supporting materials in user-friendly formats"

Response to Q10E: Applicants are encouraged to see the NOFO section on the dissemination plan (page 24 and 25 of 50). Applicant should describe a plan for how the PWMI will be disseminated to and /or used in a wider scale audience such as healthcare, community, or public health entities.

Question 11:

We will be proposing to package a clinic-community collaborative program that will be tailored for implementation through Parks and Recreation, while collecting data sufficient to inform reimbursement by 3rd party payers. There are a few aspects of the NOFO that we would like to clarify.

Q11A. The implementation pilot states it should be tested in "two new organizations." Does this refer to specific organizational entities (like the YMCA vs Parks and Recreation)? Or is it to be interpreted more broadly to be implemented in two new settings, like 2 new counties, or geographic locations? And secondly, are 2 sites sufficient? Or would more sites be preferable?

Q11B. In pulling together evidence for the "package," the NOFO is clear that it should be RCT level evidence that is a priori powered to detect a change in BMI, as evidence of efficacy. Many of these studies contain multiple components, however, and none have been able to describe WHICH are the key components needed for fidelity. Is this something that this NOFO is trying to achieve? For example, if we pull out the 26 hour threshold from the USPSTF guidelines, and MI training from BMI squared, and the nutrition and fitness group activities from MEND, can we put all of those into the package? We were concerned that, since those things have never been tested together, that specific combination may not be considered evidence-based, even though the components are. We are assuming its ok to combine as long as each element is linked clearly to RCT level evidence of effectiveness - but wanted to be sure.

Q11C. We have worked with the budget and feel we can deliver the package and a high-quality implementation study, plus strategic dissemination, within a 2.5M cap over the 5 years. However, the suggested year-to-year limits are more challenging. In our experience, the implementation period will take at least 30-36 months, to allow sufficient time for training, program start up, 12 full months of intervention, and follow up. This makes the 200K cap (particularly in year 4) difficult to meet while still funding the site directly. So the two questions are (1) how firm is the 2.5M cap and (2) how firm are the suggested yearly limits?

Response to Q11A: The size, type and/or location of the pilot sites are up to the discretion of the PI. The NOFO requires a minimum of 2 pilot sites, but additional pilot sites would also be acceptable. The NOFO does not specify that they need to be different types of organizations. Please see page 9 of 50, "The applicant will conduct pilot implementation research by identifying and collaborating with at least two additional healthcare, community or public health organizations, that serve low-income children and families aged 2 to 12 as part of their patient population. These two local organizations will use the package of training, technical assistance, evaluation and intervention manual materials in their real-world setting"

Response to Q11B: CDC cannot comment on specific approaches, programs, or designs; however, applicants are encouraged to carefully review the goals and objectives and desired outcomes described in the NOFO. However, the NOFO is not trying to test which components of various interventions work, the intent of the NOFO is take a single existing rigorously evaluated intervention and create a "package" of supporting materials such as: the curriculum, sessions, intervention activities, training materials, and implementation manuals in user friendly formats and pilot these materials in at least two new organizations.

Applicants will be evaluated during the merit review process on how well the PWMI meets the listed criteria for a solid and rigorous evidence base. The applicant should provide information to address these criteria in the research plan. The criteria are that PWMI has been: 1) rigorously evaluated such as in the form of a Randomized Control Trial l (RCT); 2) meets the USPSTF recommendations for dose and intensity; 3) is family based; 4) includes nutrition and physical activity counseling; and 5) improves BMI in children 2 to 12 years old." (See pages 8, 22 and 29-31 of 50 in the NOFO for more information on the approach, research plan and evaluation criteria).

Response to Q11C: See page 16 "It is *anticipated* that award(s) will be made under this CDC-RFA-DP19-002, with an *average* funding level of $2,500,000 per grantee over the project period…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."

Additionally, please refer to the ceiling and floor amounts on page 16 of 50. Applicants should not go above the award ceiling or below the award floor in any given budget period, but should include in their application a yearly budget that outlines the funds needed to accomplish the proposed activities.

Question 12:

[We, a city hospital] have some materials already created based on evidence based research. [The] program is in operation now – it is a provider-referred program (no cost to the family) and is a 12 week program that they deliver 3x a year. Materials are given on pediatric weight management interventions --there is a manual for the family and a flip book for the children. They work with the local YMCA now and their city government is involved.

In reading through the RFP, we were not 100 percent sure that the funding could cover materials that were already created/in existence? And perhaps we'd be able to apply and the researchers might evaluate/tweak what they have in place now to make it better or to update it? Would that be approvable or not for this award?

[Name of] Hospital was wishing to pursue this funding to help launch this program in Spencer Indiana working with that local YMCA and working with the [name of university] School of Public Health for program evaluation.

Response to Q12: This NOFO will provide an opportunity for interventions with a **solid research base** (criteria below) to be packaged and implemented within new organizations. Please see objective 1 and the anticipated outputs from objective 1 on page 10 of 50. "The anticipated outputs from objective 1 include: the package including all supporting materials in user-friendly formats, implementation manuals, training curricula, the provision of technical assistance and an evaluation and cost monitoring system". It is up to the discretion of the applicant whether they use pre-existing materials or develop new materials, however the budget should align with the activities proposed by the applicant.

Applicants will be evaluated during the merit review process on how well the PWMI meets the listed criteria for a solid and rigorous evidence base. The applicant should provide information to address these criteria in the research plan. The criteria are that PWMI has been: 1) rigorously evaluated such as in the form of a Randomized Control Trial l (RCT); 2) meets the USPSTF recommendations for dose and intensity; 3) is family based; 4) includes nutrition and physical activity counseling; and 5) improves BMI in children 2 to 12 years old." (See pages 8, 22 and 29-31 of 50 in the NOFO for more information on the approach, research plan and evaluation criteria).

Question 13:

I am interested in applying for the NOFO titled Packaging and Spreading Proven Pediatric Weight Management Interventions for Use by Low-Income Families. I have a question regarding the requirement to "…take existing evidence based PWMI, and convert them into user-friendly "packaged" materials…". Should applicants propose to package and pilot test one of the evidence based interventions originally funded under the CORD program such as MEND? I have looked at the CDC Community Health Improvement Navigator - Database of Interventions….should I be choosing one or more interventions from this database to test?

Response to Q13: The NOFO does not specify which interventions should be employed as the PWMI. It is up to the discretion of the PI to determine the specific PWMI intervention. CDC cannot comment on specific approaches, programs, or designs; however, applicants are encouraged to carefully review the goals and objectives and desired outcomes described in the NOFO.

To achieve the goal of the NOFO researchers/research teams will take a single existing evidence based PWMI and create a "package" that supports all required elements for implementing the evidence based intervention in new organizations, including all supporting materials in user-friendly formats, implementation manuals, training curricula, technical assistance and evaluation/quality control materials and pilot test them in real world settings.

Question 14:

I wanted to determine whether this FOA is a good fit for our organization, team and community? [Our organization] is a 501(c)3 community-based non profit organization;

We currently provide evidence-based Diabetes Self-Management and Prevention Education programs.to improve health outcomes for our very poor population with low health literacy, primarily immigrant; we mostly focus on their un-met social needs, provide coaching and support utilizing community navigators and thereby transform their health outcomes for diabetes.

For the above reasons, we were asked to take the lead for the community in the above FOA initiative.

For the RFA-DP-19-002, we would be working with an established researcher [name of state] University)

Our population would be comprised of children with obesity (Hispanics and African Americans) who have not made much progress in obesity prevention. These children receive their care in several local Federally Qualified Community Health Centers (FQCHC).

We have existing relationships with these FQHCs, and they are requesting to pursue this FOA that could make a difference in the obesity epidemic in our community. Primary care physicians who treat these children report that more than 60% of them are obese and several have diabetes at 13 years old.

[Our organization] is nationally accredited (by the CDC) to successfully deliver the National Diabetes Prevention Program.

From this experience, we understand packaging intervention.

And for that reason we were asked by our community to take the lead for this initiative.

- We have reviewed the evidence on childhood obesity prevention
- We have identified and developed the appropriate theory

- A [name of state university] researcher has committed to supporting our community project with the Modeling and Outcomes Processes, including feasibility/piloting/evaluation and implementation.
- We also have commitment from an external program evaluator that would be working with our team and the researcher.

Goal: To decrease childhood obesity by promoting a mild negative energy balance to decrease energy intake and or increased energy expenditure in a way that would support the children growth while covering their nutritional needs.

Given our background, experience and team: Do you envision whether this is a good fit for the CDC FOA?

Can we align with the CDC's proposed objectives for this FOA?

Response to Q14:

CDC cannot comment on specific approaches, programs, or designs; however, applicants are encouraged to carefully review the goals and objectives and desired outcomes described in the NOFO. The goal of the NOFO is not to test a new PWMI intervention. The goal is to package a single already rigorously evaluated intervention and pilot the packaged materials in at least two new organizations.

Question 15:

We are considering an application to your RFA-DP-19-002 for packaging and disseminating pediatric weight management interventions through the University of [state] Cooperative Extension Service. We have been awarded CDC cooperative agreements.

While we would partner with University of [state] HealthCare and rural health care providers on this proposal, we are not a health care provider. Would you consider the Cooperative Extension Service to be a qualified grantee for this collaborative agreement?

You may know that Cooperative Extension Service packages and disseminates evidence-based programs on healthy eating, active living, and parenting. We possess the infrastructure and capacity to do this work, but it would not be appropriate for us to apply for reimbursement for clinical services. We are accustomed to operating in the socio-ecological framework, performing implementation research, and process/outcomes evaluation.

Please let us know if we should proceed with a proposal or if only health care providers and organizations eligible for reimbursement are encouraged to apply.

Response to Q15:

CDC looks at the eligibility of the applying institution/organization in determining if an application is eligible. An applicant must meet at least one of the Special Eligibility Requirements outlined in the NOFO to be eligible for application. Refer to Section III. Eligibility Information; 3. Special Eligibility Requirements the list of eligible entities is as follows:

A city, county, or Indian tribe.

A local or tribal educational agency.

An accredited university, college, or community college.

A Federally-qualified health center.

A local health department.

A health care provider.

A community-based organization

Please use this information to determine if your organization/entity fits into any one of these categories.

Question 16:

I wanted to touch bases regarding the upcoming funding opportunity RFA-DP-19-002 "Packaging and Spreading Proven Pediatric Weight Management Interventions for Use by Low-Income Families" and the potential application of our program: [name of program]. Specifically, we are inquiring about whether the demonstrated efficacy of the program would be suitable to pursue this funding opportunity. The program is evidenced based and has a track record of positive outcomes for children between the ages of 5-16 years, which are described below.

The [name of program] program places a strong emphasis on rigorous and consistent program evaluation, and includes program implementation metrics, such as patient satisfaction and retention, as well an assessment of a broad range of outcome measures. All participants and families complete validated pre and post evaluations for behavioral health, psycho-social health and quality of life. Anthropometric measures are assessed according to CDC guidelines using standardized equipment by trained clinicians.

Based on these evaluations, more than 1500 [name of program] participants have been assessed, which has led to three peer-reviewed publications and several research presentations, to date (see attached). We have shown that participants who complete [name of program] significantly and meaningfully improve their behavioral health, including increased physical activity, reduced screen time, and a healthier home environment in relation to obesity risk factors. Nutrition behaviors also improve during the intervention with the reduction of sugar sweetened beverages and increases in fruit, vegetable, and whole grain intake. Participants have also consistently been shown to improve psycho-social health and health-related quality of life, and to significantly reduce age- and sex-adjusted BMI as a whole and across all age groups and genders. We also have long-term data from referring physician's medical records, which have

shown that BMI reductions remain significant for program completers after an average of 13 months of follow up. These long-term BMI improvements have been shown in patients from clinics in [name of state], and have now been replicated in [name of city] classes as well.

If you have time to discuss any questions you have or points of clarification, we can schedule a brief call within the next week to determine next steps in our application process.

Response to Q16: CDC cannot comment on specific approaches, programs, or designs; however, applicants are encouraged to carefully review the goals and objectives and desired outcomes described in the NOFO.

Applicants will be evaluated during the merit review process on how well the PWMI meets the listed criteria for a solid and rigorous evidence base. The applicant should provide information to address these criteria in the research plan. The criteria are that PWMI has been: 1) rigorously evaluated such as in the form of a Randomized Control Trial l (RCT); 2) meets the USPSTF recommendations for dose and intensity; 3) is family based; 4) includes nutrition and physical activity counseling; and 5) improves BMI in children 2 to 12 years old." (See pages 8, 22 and 29-31 of 50 in the NOFO for more information on the approach, research plan and evaluation criteria).

Adaptations to the RCT-tested interventions/PWMI to improve efficacy, implementation or adoption may have occurred; if so, the applicant should describe these adaptations, and how these adaptations have been evaluated to ensure efficacy. Additionally, if the PWMI has been scaled to other locations, the applicant should include this information in their research plan. Please also review the evaluation criteria on page 29-31 of 50 in the NOFO which will be used during the merit review.

Question 17:

Thanks so much for your help. We have two more questions in reference to the material on page 22.

Can evidence for the components come from cohort studies vs. RCTs?

If the components were tested in separate RCTs and found to be effective is it ok to combine the components or do they need to be tested as one package?

Response to Q17: CDC cannot comment on specific approaches, programs, or designs; however, applicants are encouraged to carefully review the goals and objectives and desired outcomes described in the NOFO. However, the NOFO is not trying to test which components of various interventions work. The intent of the NOFO is take a single existing rigorously evaluated intervention and create a "package" of supporting materials such as: the curriculum, sessions, intervention activities, training materials, and implementation manuals in user friendly formats and pilot these materials in at least two new organizations.