

Centers for Disease Control and Prevention

NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL

Reduce Health Disparities and Improve Traumatic Brain Injury (TBI) Related Outcomes Through the Implementation of CDC's Pediatric Mild TBI Guideline

RFA-CE-22-007

02/22/2022

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Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:

National Center for Injury Prevention and Control

Notice of Funding Opportunity (NOFO) Title

Reduce Health Disparities and Improve Traumatic Brain Injury (TBI) Related Outcomes Through the Implementation of CDC's Pediatric Mild TBI Guideline

Activity Code

Applications in response to this Notice of Funding Opportunity (NOFO) will be funded using the U01 activity code for a research cooperative agreement

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-CE-22-007

Assistance Listings Number(s)

93.136

Category of Funding Activity

HL - Health

NOFO Purpose

The Centers for Disease Control and Prevention (CDC) National Center for Injury Prevention and Control (NCIPC) is soliciting investigator-initiated research proposals for an implementation study to promote the adoption and integration of the "Centers for Disease Control and Prevention Guideline on the Diagnosis and Management of Mild Traumatic Brain Injury Among Children,"

hereinafter referred to as CDC's Pediatric mTBI Guideline, in a large health care system to: a) improve mild traumatic brain injury (mTBI) outcomes in children and adolescents, and b) reduce disparities in TBI-related care and outcomes.

Applicants are expected to focus on the following research questions:

1. What type of disparities in mTBI-related processes and outcomes currently exist at baseline in a healthcare system(s) prior to initiation of an intervention to systematically implement CDC's Pediatric mTBI Guideline?
2. Does an intervention aimed at systematically implementing CDC's Pediatric mTBI Guideline in a healthcare system(s) result in a reduction of health disparities, relative to baseline, vis a vis improved process and health outcomes? Applicants are encouraged to supplement the mTBI Guideline implementation with added outreach efforts to children experiencing disadvantage, and implementation strategies that address TBI-related care and health disparities identified within the health system.

For the purposes of this NOFO, mTBI-related processes and outcomes include those related to the identification and treatment of an mTBI (e.g., discharge instructions, counseling regarding return to school and return to play, communication with the school about symptoms, recovery, accommodations) as well as health outcomes. An indicator of care might be length of time between injury and diagnosis and treatment of an mTBI or the recovery trajectory of an mTBI. Disparities (health outcomes seen to a greater or lesser extent between populations) may be related to various factors of the injured child or adolescent, their family or neighborhood, or community, such as race, gender, sexual identity, disability, socioeconomic conditions, or geographic location.

The purpose of Amendment 1 to NOFO RFA-CE-22-007 is to:

- Update the NOFO Description shown on the Grants.gov Synopsis page (https://www.grants.gov/web/grants/view-opportunity.html?oppId=336420) to reflect the Purpose section of the NOFO.
- Update *Section I. Funding Opportunity Description, 1 Background and Purpose, Minority Serving Institutions*, to include the title of this section: **Minority Serving Institutions**.
- Update *Section I. Funding Opportunity Description, 2 Approach, to describe Responsiveness Criteria* related to the primary goals and objectives of the proposed research and prevention approach:

  The first paragraph of the Specific Aims section of the application must clearly describe the primary goals and objectives of the proposed research and the prevention approach that will be evaluated**. Applications that do not clearly propose to demonstrate the effectiveness of an intervention informed by CDC's Pediatric mTBI Guideline, to: a) improve mild traumatic brain injury (mTBI) outcomes in children and adolescents, and b) reduce disparities in TBI-related care and outcomes, as evidenced by the Specific Aims section of the application's research plan, will be considered nonresponsive and will not be forwarded for peer review.**

Applications must be responsive to NOFO RFA-CE-22-007 in order to be forwarded for peer review. Additional responsiveness criteria are listed in *Section III. Eligibility Information 5. Responsiveness* of this NOFO. It is the applicant's responsibility to ensure that the submitted research proposal meets all responsiveness criteria listed in *Section III. Eligibility Information 5. Responsiveness*.

- Update *Section III. Eligibility Information, 5 Responsiveness*, to clarify the responsiveness criteria for the following sections:
  - Research Objectives:
    - Corrected the spelling of Objectives, it now reads "Research Objectives"
    - To the criteria, added: "as evidenced by the Specific Aims section of the application".
  - Researcher Expertise:
    - Clarified the location for including researcher expertise, it now reads "SF-424 Biographical Sketch"
- Update Section V. Application Review Information, 4 Review and Selection Process, to include the section of the application to be reviewed in consideration of each criteria. The updated criteria now read:
  - Consideration for meritorious applications that have already identified TBI-related disparities in their implementation facilities and have described how they plan to focus on those disparities through the proposed intervention, as evidenced by the Research Strategy section of the application's research plan.
  - Consideration for meritorious applications that propose to extend Return to Play and Return to Learn protocols beyond guidance provided in discharge instructions and incorporate continued engagement between the health and education systems and sports programs, as evidenced by the Research Strategy section of the application's research plan.
  - Consideration for meritorious applications that include health systems with integrated emergency departments, examine the intervention in multiple clinical settings (primary care, ED, specialty clinics, urgent care), and allow for multi-site investigations, as evidenced by the Research Strategy section of the application's research plan.
  - Consideration for meritorious applications that propose to address inequities in TBI diagnosis and management, including studies that inform or evaluate strategies that address social and structural conditions contributing to these inequities, as evidenced by the Research Strategy section of the application's research plan.

Key Dates

Publication Date:

To receive notification of any changes to RFA-CE-22-007, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date:

01/10/2022
January 10, 2022

Application Due Date:
02/22/2022
Applications are due on the listed application due date at 5:00PM EST. Please carefully review and follow the instructions in Section IV. Application and Submission Information 9. Submission Dates and Times in order to ensure timely receipt of your application.

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

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

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

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

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

Scientific Merit Review:
06/08/2022
June 8, 2022; estimated

Secondary Review:
07/28/2022
July 28, 2022; estimated

Estimated Start Date:
09/30/2022
September 30, 2022

Expiration Date:
04/05/2022

Required Application Instructions

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

specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 20 pages.

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

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

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

Executive Summary

Purpose:

The Centers for Disease Control and Prevention (CDC) National Center for Injury Prevention and Control (NCIPC) is soliciting investigator-initiated research proposals for an implementation study to promote the adoption and integration of the "Centers for Disease Control and Prevention Guideline on the Diagnosis and Management of Mild Traumatic Brain Injury Among Children," hereinafter referred to as CDC's Pediatric mTBI Guideline, in a large health care system to: a) improve mild traumatic brain injury (mTBI) outcomes in children and adolescents, and b) reduce disparities in TBI-related care and outcomes.

Applicants are expected to focus on the following research questions:

1. What type of disparities in mTBI-related processes and outcomes currently exist at baseline in a healthcare system(s) prior to initiation of an intervention to systematically implement CDC's Pediatric mTBI Guideline?
2. Does an intervention aimed at systematically implementing CDC's Pediatric mTBI Guideline in a healthcare system(s) result in a reduction of health disparities, relative to baseline, vis a vis improved process and health outcomes? Applicants are encouraged to supplement the mTBI Guideline implementation with added outreach efforts to children experiencing disadvantage, and implementation strategies that address TBI-related care and health disparities identified within the health system.

For the purposes of this NOFO, mTBI-related processes and outcomes include those related to the identification and treatment of an mTBI (e.g., discharge instructions, counseling regarding return to school and return to play, communication with the school about symptoms, recovery, accommodations) as well as health outcomes. An indicator of care might be length of time between injury and diagnosis and treatment of an mTBI or the recovery trajectory of an mTBI. Disparities (health outcomes seen to a greater or lesser extent between populations) may be related to various factors of the injured child or adolescent, their family or neighborhood, or community, such as race, gender, sexual identity, disability, socioeconomic conditions, or geographic location.

Mechanism of Support: The funding mechanism for this Notice of Funding Opportunity (NOFO) will be a research cooperative agreement (U01).

Funds Available and Anticipated Number of Awards: CDC/NCIPC intends to commit up to $550,000 in FY 2022 to fund up to one (1) application. Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.

Budget and Project Period:
The maximum award amount will be $550,000 per award for the first 12 month budget period. This includes both direct and indirect costs. An applicant may request a project period of up to four years. The maximum total project funding amount is $2,200,000 (including both direct and indirect costs) over the expected project period length, with a maximum of $550,000 per award per year. The project period for this award is expected to run from 9/30/2022 to 9/29/2026.

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. Eligibility Information 1. Eligible Applicants* are eligible to apply.

Eligible Project Directors/Principal Investigators (PDs/PIs)
CDC does not make awards to individuals directly. Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.

Applications in which the contact Eligible PD/PI meets NIH Early Stage Investigator (ESI) status, as verified via the NIH Determination of Investigator Status process, **and** whose application has a meritorious peer review score, may be considered for prioritization during the second level of review (see *Section V. Application Review Information 4. Review and Selection Process*). For the contact PD/PI Determination of Investigator Status:

- Prior to application submission, PD/PIs are encouraged to verify and/or enter the date of their terminal research degree or the end date of their post-graduate clinical training in their eRA Commons Profile to ensure the correct identification. NIH systems will automatically calculate the status of each investigator and display it within their eRA Commons personal profile. The ESI status of the PD/PIs on any R01 or R01 equivalent application will be flagged at time of submission. Investigators should make sure their status is correctly marked in their profile. If your status is incorrect, please contact the NIH eRA Service Desk.

Number of PDs/PIs

An application may name more than one PD/PI; their names must appear on the face page of the application. However:

- One (1) principal investigator must be designated as the contact PD/PI for all correspondence related to the application.
- All PD/PIs must include their eRA Commons Identification in the Credential Field of the Senior/Key Person Profile Component of the SF-424 (R&R) Application Package.
- Institutions/organizations proposing multiple PDs/PIs must visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF-424 (R&R) Application Guide.

Number of Applications
Eligible applicant organizations may submit more than one application to this NOFO, provided that each application is scientifically distinct. However, applicant institutions can submit only one application with the same contact PD/PI. Only one application per contact PD/PI will be funded under this announcement. If two or more applications from the same contact PD/PI are received for this NOFO, the only application that will be submitted for review will be the last application received based on the document's time and date stamp in Grants.gov (http://www.grants.gov). The applicant must ensure that duplicate applications are withdrawn prior to the application review date.

Additionally, applicant institutions submitting applications with essentially the same proposed research to two or more CDC/ATSDR NOFOs will not be funded under more than one NOFO.

Application Type. NEW

Special Date(s)
A pre-application teleconference call will not be conducted for this NOFO. Applicant questions to clarify information in the text of this NOFO during the NOFO open period are strongly encouraged. Please contact via email the Scientific/Research Contact, Peer Review Contact, or the Financial/Grants Management Contact listed in *Section VII. Agency Contacts* with questions. All applicant questions (personal or application related identifying information redacted) received by December 22, 2021 and NCIPC responses to these questions will be included in an amended NOFO that will be published approximately by **January 14, 2022**. Please see *Section VII. Agency Contacts* for specific contact information.

Application Materials. See *Section IV.1* for application materials.

Section I. Funding Opportunity Description

Statutory Authority
Section 301 (a) [42 U.S.C. 241(a)] of the Public Health Service Act, and Section 391 (a)[42 U.S.C. 280b(a)] of the Public Health Service Act, as amended.

1. Background and Purpose

The National Center for Injury Prevention and Control (NCIPC) recognizes that injury, like disease, is preventable. NCIPC conducts research to develop and evaluate the effectiveness of strategies to prevent various forms of injury and mitigate the public health impacts of injury.[1]

As attention to concussion and traumatic brain injury (TBI) has grown in recent years, there has been an increase in the number of pediatric patients with concussion (also known as mild TBI, or mTBI) seen in a variety of healthcare settings.[2,3] Many providers, however, have insufficient time and training to systematically assess and manage patients with suspected mTBI,[4-6] thus limiting adoption of best practices and increasing risk for patient and public health harm. The consequence of missing an mTBI diagnosis includes the failure to recommend appropriate treatment and management; this may contribute to prolongation of symptoms and increased risk of re-injury. Even when an mTBI diagnosis is made, there are inconsistencies in assessment for prognosis, selection of management protocols, and issuance of discharge instructions. Research is needed to identify the best ways to educate providers and support clinical decision making at the point of care to facilitate pediatric mTBI diagnosis and management and improve patient outcomes.

An additional challenge in addressing the public health burden of TBI is that it is not evenly distributed. Disparities in care and outcomes have been shown for children who have experienced a TBI in relation to race/ethnicity, disability status, sex, income, geography, and insurance status. Previous research has documented a greater TBI burden for rural, American Indian/Alaskan Native, African-American, and Hispanic persons. More specifically:

> American Indian/Alaska Native children and adults have higher rates of TBI-related hospitalizations and deaths than other racial or ethnic groups.[7-10] Inequities contribute to this disparity and lead to higher rates of motor vehicle crashes, substance use, and suicide as well as difficulties in accessing appropriate healthcare.
>
> In addition to differences in rates of TBI, racial and ethnic minority groups, particularly non-Hispanic Black and Hispanic patients, are less likely to receive follow-up care and rehabilitation following a TBI compared to non-Hispanic white patients.[11-16] Racial and ethnic minority groups are also more likely to have poor psychosocial, functional, and employment-related outcomes after sustaining a TBI than non-Hispanic white patients.[17-21]
>
> People living in rural areas have a greater risk of dying from a TBI compared to people living in urban areas.[22-26] Some reasons for this disparity include:
>
> > More time needed to travel to emergency medical care.[27]
> > Less access to a Level I trauma center (the highest level of medical care).[28]
> > Difficulty getting services, such as specialized TBI care.[29,30]
>
> Children living in rural areas are more likely to get a TBI and to die as a result of this injury compared to children living in urban areas.[26] Children in rural areas may also be more likely to:

Experience delays in getting TBI-related care.[30]
Be unnecessarily transferred to another hospital for TBI-related care.[30]

Children with TBI navigate two systems- health systems and school systems. There are challenges, inconsistencies, and gaps in care for children with TBI, particularly for children who are transitioning to school after acute care.[31] Methods used to assess factors associated with TBI diagnosis and prognosis – such as the child's medical history, current school performance, and family circumstances – are variable. Adequate and consistent assessment of such factors is important to help identify children at risk for long-term effects.[31] In addition, communication of medical information to parents and school personnel is inconsistent, which contributes to gaps in care[31] and potentially poorer health, education, and social outcomes for children.

Data from a large pediatric healthcare system revealed that the majority of children with mTBI are seen in primary care, compared to emergency departments and specialty clinics.[2] This finding highlights the need to provide education and clinical decision support in primary care pediatric clinics in particular. Preliminary data suggest that clinical decision support tools can be effectively implemented in primary care practices to assist with diagnosis, management, and treatment of pediatric TBI.[32] For example, tools within the electronic health record (EHR) can alert providers to conduct exams not routinely completed, such as vision exams, and encourage discussion of Return to Learn (RTL) and Return to Play (RTP) protocols with parents and children. One study found that implementation of clinical decision support tools in the EHR, combined with systematic clinician training, increased documentation of recommended protocols for children with an mTBI diagnosis.[32]

While clinician education and EHR-based clinical decision support has been shown to improve process-related outcomes,[32] the effect of these efforts have not yet been tested in relation to patient health, education, and social outcomes. Further work is also needed to understand the best mechanisms for enhancing communication among health and school systems and sports organizations to improve implementation of RTL and RTP protocols.

Evidence-based recommendations have emerged to inform the development of protocols that can assist clinicians in the diagnosis and management of pediatric mTBI. For example, NCIPC researchers, in conjunction with the NCIPC Board of Scientific Counselors, established the Pediatric mTBI Guideline workgroup to systematically review the literature and draft recommendations for providers related to the diagnosis and management of pediatric mTBI. NCIPC researcers used these evidence-based recommendations to develop CDC's Guideline for Pediatric mTBI Diagnosis and Management.[33] Since its publication in November 2018, this Guideline has been used to help educate and support clinicians in implementing best practices for pediatric mTBI diagnosis and management. The development and systematic implementation of evidence-based guidelines hold promise for increasing the use of state of the art care in a uniform way. The provision of uniform, state of the art care is a potential means to reduce health disparities when implemented in places that serve groups experiencing disadvantage.

As previously mentioned, previous research has noted that the public health burden of TBI includes disparities in care and outcomes for children who have experienced a TBI. Disparities have been identified related to race/ethnicity, disability status, sex, income, geography, and

insurance status. The social and structural conditions in which people are born, grow, live, work and age can be shaped by the distribution of resources, which is influenced in part by policy. These social determinants of health (e.g., concentrated poverty, structural racism, high rates of unemployment and community violence, weak social connectedness, limited access to high-quality education and/or affordable, high-quality childcare) contribute to health inequities, including the differences in health status seen across population groups and communities[34]. Research is needed to better address disparities in diagnosis and management of pediatric mTBI.

Purpose:
The Centers for Disease Control and Prevention (CDC) National Center for Injury Prevention and Control (NCIPC) is soliciting investigator-initiated research proposals for an implementation study to promote the adoption and integration of the "Centers for Disease Control and Prevention Guideline on the Diagnosis and Management of Mild Traumatic Brain Injury Among Children," hereinafter referred to as CDC's Pediatric mTBI Guideline, in a large health care system to: a) improve mild traumatic brain injury (mTBI) outcomes in children and adolescents, and b) reduce disparities in TBI-related care and outcomes.

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Funds are available for an implementation study to promote the adoption and integration of the Guideline into routine health care to improve the impact on population health. Implementation should focus on groups for which there are known disparities in TBI-related outcomes. Funds are not available to support TBI-related diagnostics or care activities.

Minority Serving Institutions: This NOFO seeks diversity among applicant institutions, research investigators, and partnering organizations to ensure researcher experience and research

outcomes are applicable and beneficial to all segments of our population and social ecology. Applicants from or collaborating with Minority Serving Educational Institutions (MSIs) representative of and serving the community participating in the evaluation are highly encouraged. For the purpose of this NOFO, MSIs include Hispanic Serving Institutions (HSIs), Historically Black Colleges and Universities (HBCUs), Tribal Colleges and Universities (TCUs), and Alaska Native and Native Hawaiian Serving Institutions, as defined by the U.S. Department of Education. Meritorious applications from eligible MSIs or eligible institutions collaborating with MSIs, as evidenced by MSI inclusion in the SF-424 Senior/Key Personnel form, may be considered during the second level of review to broaden distribution of awards (see *Section V. Application Review Information 4. Review and Selection Process*).

Healthy People 2030 and other National Strategic Priorities

The proposed research addresses the NCIPC Research Priority of evaluating the effectiveness of strategies for preventing all forms of traumatic brain injury (TBI) and enhance the recognition and management of mild TBI in clinical and community settings[1], and is described in the NCIPC's research priorities (https://www.cdc.gov/injury/researchpriorities/index.html).

The proposed research also addresses "Healthy People 2030" goals for injury and violence prevention and improving the health as described in https://www.health.gov/healthypeople. Specifically, this NOFO supports the following objectives:

- Reduce fatal injuries— IVP-01
- Reduce emergency department visits for non-fatal injuries — IVP-02
- Reduce emergency department visits for non-fatal unintentional injuries — IVP-04
- Reduce fatal traumatic brain injuries —IVP-05

Public Health Impact

The increase in the number of pediatric patients with mTBI combined with challenges in providing evidence-based diagnosis and management strategies and the uneven use of those strategies across the country are a significant public health problem. The goals of this research funding are to demonstrate the effectiveness of an intervention informed by an evidence-based guideline to: a) improve mTBI outcomes in children and adolescents, and b) reduce disparities in TBI-related care and health outcomes.

Relevant Work

CDC's research and programs work to prevent TBI and help people to better recognize, respond, and minimize the consequences of TBI. Working with states and other partners, CDC supports evidence-based strategies to prevent TBI and promote healthy lifestyles that can improve the quality of life for people living with TBI. Recently, NCIPC developed research priorities to identify effective strategies for enhancing management of mTBI in clinical settings. These activities are outlined in the CDC NCIPC Research Priorities report that can be found at: http://www.cdc.gov/injury/researchpriorities/index.html.

The CDC NCIPC Board of Scientific Counselors established the Pediatric mTBI Guideline workgroup to systematically review the literature and draft recommendations for providers

related to the diagnosis and management of pediatric mTBI. These evidence-based recommendations were developed into CDC's Pediatric mTBI Guideline available here: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7006878/ Since its publication, this Guideline has been used to help educate and support clinicians in implementing best practices for pediatric mTBI diagnosis and management. CDC has developed a suite of tools for healthcare providers, patients, and their families to implement the Guideline recommendations. Those tools are available here: https://www.cdc.gov/traumaticbraininjury/PediatricmTBIGuideline.html

For over a decade, the Injury Center's HEADS UP campaign has played a prominent role in the public health response to concussion. HEADS UP is a series of educational initiatives that all have a common goal: Protect kids and teens by raising awareness and informing action to improve prevention, recognition, and response to concussion and other serious brain injuries. HEADS UP educational materials are designed to help support individuals and organizations with their concussion reduction efforts and are available in a variety of formats. CDC has created practical, easy-to-use clinical information and tools for health care providers and their patients, including free online training that offers free continuing education credits, available at https://www.cdc.gov/headsup/providers/index.html.

References:

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2. Approach

For NOFO RFA-CE-22-007, applicants are expected to propose a rigorous study design (e.g., randomized controlled trial, quasi-experiment) to evaluate the implementation of CDC's Pediatric mTBI Guideline. The applicant is expected to implement all facets of the Guideline including clinician education, electronic clinical decision support, and customized discharge instructions. Applicants should also employ enhanced outreach to children experiencing disadvantage and their families/schools/community organizations, and consider enhanced connections to schools to improve a child's adjustment upon their return to school. Applicants are expected to first assess and analyze mTBI-related processes and outcomes to delineate existing disparities (that is, establish a baseline) prior to implementation of the Guideline, and to implement the Guideline in a manner that seeks to reduce disparities. Applicants who can articulate already-identified TBI-related disparities in their applications, then indicate how they plan to subsequently focus on those disparities through the proposed intervention, are preferred.

Applicants are expected to clearly justify their choice of health-care system. Applicants are expected to demonstrate the ability to measure both changes in mTBI outcomes and changes in health disparities. Applicants are also expected to describe the potential generalizability of their

results to other health-care systems.

Applicants are expected to study adoption, integration, and patient outcomes of an intervention focused on improving personalized diagnosis, management, and treatment of pediatric mTBI based largely on evidence-based recommendations outlined in CDC's Pediatric mTBI Guideline.[33] For the purpose of this NOFO the 'intervention' consists of clinician education, electronic clinical decision support, customized discharge instructions, enhanced outreach to children experiencing disadvantage and their families/schools/community organizations, and enhanced connections to schools to improve a child's adjustment upon their return to school. Discharge instructions are expected to include protocols outlining parent-friendly instructions describing best practices for the management of symptoms at home and at school, including Return to Learn (RTL) and Return to Play (RTP) protocols. The education, support, and discharge instructions are expected to be designed for implementation in primary care and/or emergency department settings, but could also include specialty care (e.g., sports medicine, and clinics that serve children with mTBI) and urgent care. Projects that extend RTL and RTP protocols beyond guidance provided in discharge instructions and incorporate continued engagement between the health and education systems and sports programs, are preferred.

Applicants should take care to ensure appropriateness of the control/comparison group, and analytic plans should anticipate and evaluate the effects of threats to the internal and external validity of the research design, including adjusting for history effects (e.g., changes in health system, state, or federal policies or guidelines specifying protocols of care over time). Applicants should include research plans that describe the research questions, study design, hypotheses, sample to be studied, recruitment strategies, data collection measures, sources, time points, procedures, analytic strategy, and estimated sample size and power for each proposed hypothesis. Applicants are expected to identify key outcomes for each research question to determine whether the intervention improves clinical care and health outcomes and reduces health disparities. Examples of primary outcomes include reductions in length of time between injury diagnosis and treatment and symptom resolution time, improved recovery trajectories, reduction in concussion-related complications (e.g., educational difficulties), greater adherence to RTL and RTP recommendations, better academic performance, and increased utilization of needed accommodations and services. Examples of secondary outcomes include: improvement in the sensitivity and specificity of TBI diagnosis, utilization of best practices in diagnosis (e.g., visual-oculomotor screening, use of validated symptom inventories) and management (e.g., provision of RTL and RTP instructions; increased communication with coaches, teachers, parents), increase in follow-up by patients and their caregivers (e.g. follow-up medical appointments when needed, monitoring of symptoms by patients and their caregivers). Applicants should attend to methods for outcome measurement that reduce bias (e.g., inclusion of multiple forms of measurement, such as through electronic health record documentation as well as patient interviews/surveys). Research plans that include health systems with integrated emergency departments, examine the intervention in multiple clinical settings (primary care, ED, specialty clinics, urgent care), and allow for multi-site investigations are preferred.

It is anticipated that before implementation of the intervention applicants will propose to obtain information on disparities within their healthcare system for TBI patients, and then use that information to inform intervention implementation.

Funds are available for an implementation study to promote the adoption and integration of the Guideline into routine health care to improve the impact on population health. Implementation should focus on groups for which there are known disparities in TBI-related outcomes. Funds are not available to support TBI-related diagnostics or care activities.

The first paragraph of the Specific Aims section of the application must clearly describe the primary goals and objectives of the proposed research and the prevention approach that will be evaluated. **Applications that do not clearly propose to demonstrate the effectiveness of an intervention informed by CDC's Pediatric mTBI Guideline, to: a) improve mild traumatic brain injury (mTBI) outcomes in children and adolescents, and b) reduce disparities in TBI-related care and outcomes, as evidenced by the Specific Aims section of the application's research plan, will be considered nonresponsive and will not be forwarded for peer review.**

Applications must be responsive to NOFO RFA-CE-22-007 in order to be forwarded for peer review. Additional responsiveness criteria are listed in *Section III. Eligibility Information 5. Responsiveness* of this NOFO. It is the applicant's responsibility to ensure that the submitted research proposal meets all responsiveness criteria listed in *Section III. Eligibility Information 5. Responsiveness*.

Objectives/Outcomes
The primary objective of this research is to demonstrate improved mTBI outcomes in children (health, educational, and social) and a reduction in disparities in outcomes between identified subpopulations.

Primary Outcomes
Examples of specific primary outcomes include reductions in length of time between injury diagnosis and treatment and symptom resolution time, improved recovery trajectories, reduction in concussion-related complications (e.g., educational difficulties), greater adherence to RTL and RTP recommendations, better academic performance, and increased utilization of needed accommodations and services. Other primary outcomes should include any disparities in health or educational outcomes identified through the pre-intervention assessment. Other primary outcomes should include any disparities in processes identified through the pre-intervention assessment.

Secondary Outcomes
Examples of secondary outcomes include: improvement in the sensitivity and specificity of TBI diagnosis, utilization of best practices in diagnosis (e.g., visual-oculomotor screening, use of validated symptom inventories) and management (e.g., provision of RTL and RTP instructions; increased communication with coaches, teachers, parents), increase in follow-up by patients and their caregivers (e.g. follow-up medical appointments when needed, monitoring of symptoms by patients and their caregivers). Applicants should attend to methods for outcome measurement that reduce bias (e.g., inclusion of multiple forms of measurement, such as through electronic health record documentation as well as patient interviews/surveys).

Rigorous evaluation designs. Evaluations must use rigorous experimental or quasi-experimental

designs that are able to demonstrate the impact of the approach on the proposed outcomes of interest. For the purposes of this research opportunity, rigorous evaluation designs include those that utilize experimental designs (randomized controlled trials) or rigorous quasi-experimental designs (e.g., comparative interrupted time series design, difference-in- differences, instrumental variable methods, regression discontinuity, regression point displacement, stepped wedge, propensity-score matching, matched comparison groups).

Data collection, acquisition, and analysis. Applicants must identify and describe appropriate data sources and provide evidence of their ability to acquire and/or collect data of sufficient quantity and quality to conduct a rigorous evaluation. Applications should clearly describe and justify the proposed sampling methods, sample size, power estimates, and data collection methods for the proposed outcome(s). The timeline for data acquisition (requests for extant data and or primary data collection) must be specified.

Protection of Human Subjects and Personally Identifiable Information
The Research Strategy section of the application is expected to clearly describe the type, source, access to, and protections of the data and human subjects participating in the study. Access to non-publicly available, previously collected data must be clearly described in the Research Strategy and documented with a signed Data Sharing Agreement or Letter of Support. Access to publicly available, previously collected data must be clearly described in the Research Strategy.

Protection of previously collected data includes, but is not limited to, protection of personally identifiable information from loss and/or misuse.

The application is expected to identify each performance site that will be conducting human subjects research and include the FWA number for the applicant institution and each performance site. Research conducted with more than one institution will be expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations. See *Section IV. Application and Submission Information, 10 Funding Restrictions, Human Subjects* for details.

Considerations for Responsiveness:
Applications must be scientifically responsive to NOFO RFA-CE-22-007 in order to be forwarded for peer review. Additional responsiveness criteria are listed in Section III. Eligibility Information 5. Responsiveness of this NOFO. It is the applicant's responsibility to ensure that the submitted research proposal meets all responsiveness criteria listed in *Section III. Eligibility Information 5. Responsiveness*.

Target Population
The population for the intervention should be children and adolescents up to 18 years of age. A particular focus on an identified group(s) for which there are known disparities in TBI-related outcomes (e.g., American Indian Alaska Native, African-American, Latino, or rural populations) is required. Applicants must ensure that their patient population is sufficiently diverse in order to detect differences.

Collaboration/Partnerships
It is expected that for all applications, the applicant organization and contact PI will provide the scientific and technical leadership necessary to conduct the proposed research throughout the entire project period. It is expected that the proposed research work plan described in the Research Strategy section of the application and the SF-424 Research and Related Budget will demonstrate the applicant organization's leadership and involvement throughout the entirety of the project period. The applicant organization cannot serve as a "pass through" to fund another entity to conduct the majority of the research or provide the scientific or technical leadership necessary to complete the proposed research project.

Applicants are expected to partner with administrators and clinicians within health systems. In addition, there may be a need to partner with tribal organizations (if the subpopulation of interest is American Indian Alaska Native children), as well as vendors for electronic health record (EHR) systems. Partnerships should also include schools and youth sports programs to enhance Return to Learn and Return to Play protocols.

The application must clearly describe roles and responsibilities of each partnering entity. This includes demonstration of the applicant's access to planned data sources and study populations, and all partnerships necessary to complete the proposed project.

The Research Strategy section of the application is expected to clearly describe the roles and responsibilities of each research team member individually and each participating entity. This includes describing how the partnership will allow the applicant to complete the proposed work. The Research Strategy section of the application must clearly describe the nature and extent of the proposed partnership, including the roles and responsibilities of the Principal Investigator(s) and of the outside entities or partner agencies, the existing working relationship, plans for the proposed research, the nature and extent of the involvement to be provided by the applicant institution and outside entity, the outside entity's scope of work, and how the partnership will ensure implementation and sustainability of the proposed evaluation. The Research Strategy section must clearly describe all data sources and the partnerships that are in place to assure data access for all proposed analyses to be completed within the project period.

The roles and responsibilities described for each partnering entity must be substantiated with a signed Data Sharing Agreement, Letter or Support (LOS), or Memorandum of Understanding (MOU), and be included in the Letter of Support section of the application. The Data Sharing Agreement, Letter of Support (LOS), or Memorandum of Understanding (MOU) must describe the partner's commitment of resources, time, and personnel to the proposed research. Applications that do not include a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding from each partnering entity may not be recommended for funding (see ***Section V. Application Review Information, 4 Review and Selection Process***).

Applications will be evaluated during peer review on:

- The extent to which the Research Strategy section clearly describes the roles and responsibilities of each partner involved in data collection and/or the effectiveness evaluation.

- The extent to which the Research Strategy clearly describes the working relationships between the applicant institution and all partner organizations.
- The extent to which the Research Strategy clearly describes the involvement and scope of work each partner is willing to complete to ensure the success of the proposed research within the proposed project period.
- The extent to which the relationships and activities of the partnerships described in the Research Strategy, are documented by a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding that clearly delineates the intent and capabilities of each partnership.

Applications that do not include a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding from each partnering entity or source of data described in the Research Strategy section of the application may not be recommended for funding (see ***Section V. Application Review Information, 4 Review and Selection Process***). It is incumbent on the applicant to clearly describe each contribution of each partnership to the proposed research in the Research Strategy and document the intent and capabilities of each partnership with a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding.

Minority Serving Institutions: This NOFO seeks diversity among applicant institutions, research investigators, and partnering organizations to ensure researcher experience and research outcomes are applicable and beneficial to all segments of our population and social ecology. Applicants from or collaborating with Minority Serving Educational Institutions (MSIs) representative of and serving the community participating in the evaluation are highly encouraged. For the purpose of this NOFO, MSIs include Hispanic Serving Institutions (HSIs), Historically Black Colleges and Universities (HBCUs), Tribal Colleges and Universities (TCUs), and Alaska Native and Native Hawaiian Serving Institutions, as defined by the U.S. Department of Education. Meritorious applications from eligible MSIs or eligible institutions collaborating with MSIs, as evidenced by MSI inclusion in the SF-424 Senior/Key Personnel form, may be considered during the second level of review to broaden distribution of awards (see *Section V. Application Review Information 4. Review and Selection Process*).

This NOFO encourages the inclusion of early-stage investigators as members of the SF-424 Senior/Key Personnel research team to help build experience and expertise in violence prevention research.

Applications should demonstrate that the research staff have the necessary skills and experience to ensure quality and timeliness of proposed activities. The participation of students and other researchers-in-training is encouraged. Applicants planning to incorporate training and/or mentorship roles into their research activities should describe the plans for the recruitment, training, and supervision of trainees/mentees and the ongoing quality assurance of their scientific products.

Evaluation/Performance Measurement

Applicants must evaluate and document performance during each stage of the research process, including partnership development, study development, recruitment, intervention planning, intervention implementation, process and outcome measurement, data collection, retention, and

data analysis. The application is expected to include a clear description of relevant performance measures for each stage of the research project. Comparison of actual progress to the performance measures are expected to document whether the research is progressing appropriately and in a timely manner, and whether the research activities are of high scientific quality.

The plan must be able to demonstrate the feasibility of accomplishing the proposed project objectives. Measures of effectiveness must relate to the goals stated in the "Purpose" section of this announcement and be able to measure the intended outputs and outcomes described. Outcomes to be evaluated should be clearly specified. If applicable, performance measures should include the number of participants recruited into the study, the participation rate, and types of samples collected.

Translation Plan

The application is expected to clearly describe the potential for widespread dissemination, implementation, and sustainability of the proposed interventions. Investigators are expected to collaborate with CDC investigators on the development of a translation plan for the research findings. The plan should describe how the results will be disseminated to achieve the greatest impact. Publication of findings in peer-reviewed journals is anticipated. Investigators should prepare a publicly available guide as to how the research findings could be translated directly into health systems to integrate evidence-based recommendations for diagnosis and management of pediatric mTBI into clinical care, as well as lessons learned about using these recommendations as a means to reduce health disparities among children who experience a TBI.

Grant recipients will be required to attend at least one reverse site visit in Atlanta with CDC/NCIPC staff during the duration of performance to review their progress and findings and to discuss opportunities for widespread dissemination of their research achievements and lessons learned. This must be reflected in the grantee's budget in their application submitted in response to this NOFO.

3. Funding Strategy

N/A

Section II. Award Information

Funding Instrument Type:

CA (Cooperative Agreement)

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

Application Types Allowed:

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

Estimated Total Funding:
$2,200,000
The maximum award amount will be $550,000 per award for each 12 month budget periods. This includes both direct and indirect costs. An applicant may request a project period of up to four years. The maximum total project funding amount is $2,200,000 (including both direct and indirect costs) over the expected project period.

Anticipated Number of Awards:
1
Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling:
$550,000
Per Budget Period

Award Floor:
$200,000
Per Budget Period

Total Period of Performance Length:
4 year(s)

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

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

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

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

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

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

23 (Small businesses)

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

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

Additional Eligibility Category:

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

Hispanic-serving Institutions

Historically Black Colleges and Universities (HBCUs)

Tribally Controlled Colleges and Universities (TCCUs)

Alaska Native and Native Hawaiian Serving Institutions

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Other:

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

Faith-based or Community-based Organizations

Regional Organizations

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

2. Foreign Organizations

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

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

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

3. Additional Information on Eligibility

See *Section III. Eligibility Information*

4. Justification for Less than Maximum Competition

Not Applicable

5. Responsiveness

It is the applicant's responsibility to ensure that the application meets all responsiveness criteria listed in this section.

- Research Objectives:

  There must be an overall match between the proposed research objectives as described in the Specific Aims section of the application and the research objectives described in the Background and Purpose, Approach, and Objectives and Outcomes sections of this funding announcement. The research objectives of this NOFO are to demonstrate the effectiveness of a clinical intervention informed by CDC's Pediatric mTBI Guideline, to: a) improve mild traumatic brain injury (mTBI) outcomes in children and adolescents, and b) reduce disparities in TBI-related care and outcomes.

  - The first paragraph of the Specific Aims section of the application must clearly describe the primary goals and objectives of the proposed research and the prevention approach that will be evaluated. **Applications that do not clearly propose to demonstrate the effectiveness of an intervention informed by CDC's Pediatric mTBI Guideline, to: a) improve mild traumatic brain injury (mTBI) outcomes in children and adolescents, and b) reduce disparities in TBI-related care and outcomes, as evidenced by the Specific Aims section of the application, will be considered nonresponsive and will not be forwarded for peer review.**

- Researcher Expertise

The SF-424 Biographical Sketch for the PI or Co-Investigator(s) must include documentation of expertise in the area of traumatic brain injury diagnosis or management that is reflected in the application's research strategy section. The knowledge, experience, and expertise necessary to conduct this research and achieve proposed objectives must be documented with at least one first-authored, peer-reviewed publication as defined by the NIH National Library of Medicine in the relevant area of TBI diagnosis or management, or by serving as a principal investigator on a research grant in TBI diagnosis or management research. Experience requirements may be demonstrated through the combined experiences of a Principal and Co-Investigator (if applicable). The citation of the relevant publication(s) or research experience must be clearly identified (by bold text or highlight) in the appropriate SF 424 Biographical Sketch. **Applications that do not include documentation to meet this requirement will be considered non-responsive and will not be forwarded for peer review.**

6. Required Registrations

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

PLEASE NOTE: For applications due on or after April 4, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. In preparation for the federal government's April 4, 2022, transition from the Data Universal Numbering System (DUNS) to the Unique Entity Identifier (UEI), applicants must obtain a UEI. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

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

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

All Senior/Key Personnel (including Program Directors/Principal Investigators (PD/PIs) must

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

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

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

PLEASE NOTE: For applications due on or after April 4, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. In preparation for the federal government's April 4, 2022, transition from the Data Universal Numbering System (DUNS) to the Unique Entity Identifier (UEI), applicants must obtain a UEI. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

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

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

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

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

9. Cost Sharing

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

10. Number of Applications

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

Eligible applicant organizations may submit more than one application to this NOFO, provided that each application is scientifically distinct. However, applicant institutions can submit only one application with the same contact PD/PI. Only one application per contact PD/PI will be funded under this announcement. If two or more applications from the same contact PD/PI are received for this NOFO, the only application that will be submitted for review will be the last application received based on the document's time and date stamp in Grants.gov (http://www.grants.gov). The applicant must ensure that duplicate applications are withdrawn prior to the application review date.

Additionally, applicant institutions submitting applications with essentially the same proposed research to two or more CDC/ATSDR NOFOs will not be funded under more than one NOFO.

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

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

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

2. Content and Form of Application Submission

Applicants must use FORMS-G application packages for due dates on or after April 4, 2022 and must use FORMS-F application packages until April 3, 2022.

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

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

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

Please use the form and instructions for SF424 (R&R) Form F. Applicants must use FORMS-F application packages until April 3, 2022.

3. Letter of Intent

Due Date for Letter Of Intent 01/10/2022

01/10/2022

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 NCIPC 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 (organization)
- Description of the research topic
- Descriptive title of the proposed research
- Name, address, and telephone number of the contact PD/PI
- Name of other key personnel
- Participating institutions
- Number and title of this notice of funding opportunity announcement (NOFO)

The letter of intent should be sent electronically to:

Mikel Walters, PhD
Scientific Review Official
Extramural Research Program Operations
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention (CDC)
Email: mwalters@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

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

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

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

Other Research Plan Sections

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

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

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

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

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

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

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

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

Applicants must use FORMS-G application packages for due dates on or after April 4, 2022 and must use FORMS-F application packages until April 3, 2022.

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

Please use the form and instructions for SF424 (R&R) Form F. Applicants must use FORMS-F application packages until April 3, 2022.

6. Appendix

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

Up to 5 PDF files of supporting materials for the Research Plan may also be included in the appendix as described below (7. Page Limitations). The appendix has a total maximum page limit of 25 pages.

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

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 20 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 25 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

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

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

Applicants must use FORMS-G application packages for due dates on or after April 4, 2022 and must use FORMS-F application packages until April 3, 2022.

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

Please use the form and instructions for SF424 (R&R) Form F. Applicants must use FORMS-F application packages until April 3, 2022.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if

errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes. Applicants will use a platform or system to submit applications.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Due Date for Applications 02/22/2022

02/22/2022
Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Funding Restrictions

Expanded Authority:

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

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

Public Health Data:

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

Data Management Plan:

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

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

Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate.

For further information, please see: https://www.cdc.gov/grants/additional-requirements/ar-25.html

Human Subjects:

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

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

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

Protection of Human Subjects and Personally Identifiable Information
The Research Strategy section of the application is expected to clearly describe the type, source, access to, and protections of the data and human subjects participating in the study. Access to non-publicly available, previously collected data must be clearly described in the Research Strategy and documented with a signed Data Sharing Agreement or Letter of Support. Access to publicly available, previously collected data must be clearly described in the Research Strategy.

Protection of previously collected data includes, but is not limited to, protection of personally identifiable information from loss and/or misuse.

The application is expected to identify each performance site that will be conducting human subjects research and include the FWA number for the applicant institution and each performance site. Research conducted with more than one institution will be expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations. See *Section IV. Application and Submission Information, 10 Funding Restrictions, Human Subjects* for details.

Data Management Plan
Applicants should develop and include, as part of the application's Resource Sharing Plan section of the PHS 398 Research Plan Component, a data management plan that meets the requirements of AR-25 using their own template. Applicants funded under this NOFO will be required to use NCIPC's Data Management Plan Template, OMB NO: 0920-1301 (Exp. Date: 06/30/2023) to make revisions to the DMP as required during the award's project period.

Indirect Cost Rate Agreement
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.

11. Other Submission Requirements and Information

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

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

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

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

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

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

Application Submission

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

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

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

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

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

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

PLEASE NOTE: For applications due on or after April 4, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. In preparation for the federal government's April 4, 2022, transition from the Data Universal Numbering System (DUNS) to the Unique Entity Identifier (UEI), applicants must obtain a UEI. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

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

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

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

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

Section V. Application Review Information

1. Criteria

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

Overall Impact

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

Scored Review Criteria

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

Significance

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

To what extent will the proposed clinician education, electronic clinical decision support tools, and discharge instructions advance the implementation of evidence-based and evidence-informed recommendations for pediatric mTBI diagnosis and management in clinical practice?

If successfully implemented, what is the likelihood that the proposed intervention will increase consistency among healthcare providers for the diagnosis and management of mTBI in children?

To what extent will the proposed study advance the knowledge about the extent to which intervention improves clinical outcomes?

To what extent does the proposed study have the capacity to advance the knowledge about the extent to which the intervention reduces disparities in care and outcomes among children who experience a TBI?

To what extent do the research plans include integrated health systems and examine the intervention across clinical settings (primary care, ED, specialty clinics, urgent care), and allow for multi-site investigations?

Investigator(s)

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

To what extent does the application clearly demonstrate that the research team has the experience in pediatric mTBI diagnosis and management to conduct the proposed research?

To what extent does the application clearly demonstrate that the research team has the experience in health disparities research to conduct the proposed research?

If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise that would contribute to the aims of this NOFO?

Have the investigators demonstrated an ongoing record of accomplishments that have advanced their field(s)?

Is there evidence of a past collaboration with the proposed research team to support the success of the proposed project?

What is the research team's experience in conducting evaluation of clinical training and/or interventions to determine effect and impact on outcome measures of interest?

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?

To what extent does the proposal include innovative methods for assessing implementation and use of the intervention components (clinician training, decision support, and discharge instructions) and obtaining feedback?

To what extent does the proposal include innovative methods for assessing disparities and health, social, and education outcomes?

To what extent does the proposal include innovative approaches for enhancing linkages among health systems, education systems, and sports programs to foster Return to Play and Return to Learn protocols?

Projects that propose extending RTL and RTP protocols beyond guidance provided in discharge instructions and incorporating engagement between the health and education systems and sports programs are encouraged but not required.

To what extent does the proposal articulate already-identified disparities in TBI -related processes and outcomes, and a plan to address those disparities?

Is the proposed research innovative or novel and yet offer a reasonable potential of meeting the Purpose and Research Objectives of this NOFO?

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?

To what extent does the applicant propose using a rigorous evaluation design?

To what extent does the applicant demonstrate the ability to access the necessary data for the proposed evaluation (e.g., health, social, educational data)? Are these data appropriate for the proposed research? Does the applicant propose a study with an adequate sample size and power to test the proposed hypotheses? Have the applicants demonstrated that the proposed population to be studied is sufficiently diverse to examine research questions related to health disparities? Are measures of disparities sufficiently robust?

To what extent does the application specify how recruitment strategies will be sufficient to achieve the projected sample size?

To what extent does the proposal lay out a program that has realistic potential for scalability (i.e.

broader dissemination)?

To what extent does the applicant's research plan include obtaining information related to the feasibility of implementation and fidelity to the intervention?

To what extent does the applicant's research plan include obtaining suitable metrics to establish the presence of health disparities among pediatric TBI patients?

To what extent does the applicant's research plan include obtaining feedback (from e.g., groups experiencing disadvantage, clinicians, parents, coaches, school personnel)?

To what extent does the research plan include integrated health systems and examine the intervention across clinical settings (e.g., primary care, ED, specialty clinics, urgent care) and allow for multi-site investigations? Do the proposed outcome measures appropriately address the study aims?

To what extent does the Research Strategy section of the application clearly describe the roles and responsibilities of each partner involved in data collection and/or the effectiveness evaluation?

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?

Are the partnerships necessary and critical for successfully completing the research clearly described in the Research Strategy section of the application?

To what extent does the application clearly describe the working relationships between the research institution and all partner organizations?

Does the application clearly describe the involvement and scope of work the community organizations, community leaders, and other partners are willing to commit to ensure the successful implementation and evaluation of the prevention strategies, including providing or facilitating access to relevant study participants, implementation or outcome data?

To what extent is the nature of each entity’s involvement and existing collaborations sufficient for the successful completion of the project as a whole?

To what extent does the proposed study include a population(s) experiencing disadvantage (e.g., lower socioeconomic status settings, rural residents)?

To what extent does the Research Strategy clearly describe the working relationships between the applicant institution and all partner organizations?

To what extent does the Research Strategy clearly describe the involvement and scope of work each partner is willing to complete to ensure the success of the proposed research within the proposed project period?

To what extent are the relationships and activities of the partnerships described in the Research Strategy documented by a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding that clearly delineates the intent and capabilities of each partnership?

2. Additional Review Criteria

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

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

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

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

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

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following four points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable

restraining devices; and 4) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VAChecklist.pdf).

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

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

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

3. Additional Review Considerations

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

Applications from Foreign Organizations
N/A

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the

indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

4. Review and Selection Process

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

As part of the scientific peer review, all applications:

- Will undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

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

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Consideration for meritorious applications that include signed Data Sharing Agreements, Letters of Support, or Memorandum of Understanding for each partnership described in the Research Strategy section of the application.
- Consideration for meritorious applications that have already identified TBI-related disparities in their implementation facilities and have described how they plan to focus on those disparities through the proposed intervention, as evidenced by the Research Strategy section of the application's research plan.
- Consideration for meritorious applications that propose to extend Return to Play and Return to Learn protocols beyond guidance provided in discharge instructions and incorporate continued engagement between the health and education systems and sports programs, as evidenced by the Research Strategy section of the application's research plan.
- Consideration for meritorious applications that include health systems with integrated emergency departments, examine the intervention in multiple clinical settings (primary care, ED, specialty clinics, urgent care), and allow for multi-site investigations, as evidenced by the Research Strategy section of the application's research plan.
- Consideration for meritorious applications that propose to address inequities in TBI diagnosis and management, including studies that inform or evaluate strategies that address social and structural conditions contributing to these inequities, as evidenced by the Research Strategy section of the application's research plan.
- Consideration for applicant organizations from or conducting research in collaboration or partnership with Minority Serving Educational Institutions (MSIs) i.e., Hispanic Serving Institutions (HSIs), Historically Black Colleges and Universities (HBCUs), Tribal

Colleges and Universities (TCUs), or Alaska Native and Native Hawaiian Serving Institutions, as defined by the U.S. Department of Education, and as evidenced by MSI inclusion in the SF-424 Senior/Key Personnel form, to broaden distribution of awards.

- Consideration for applications in which the contact PD/PI meets NIH Early Stage Investigator (ESI) status, as verified by the NIH Determination of Investigator process, to broaden distribution of awards.

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

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

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

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

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

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

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

PLEASE NOTE: For applications due on or after April 4, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. In preparation for the federal government's April 4, 2022, transition from the Data Universal Numbering System (DUNS) to the Unique Entity Identifier (UEI), applicants must obtain a UEI. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

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

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

2. CDC Administrative Requirements

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

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

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-3: Animal Subjects Requirements
AR-9: Paperwork Reduction Act Requirements
AR-10: Smoke-Free Workplace Requirements
AR-11: Healthy People 2030
AR-12: Lobbying Restrictions
AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
AR-14: Accounting System Requirements
AR-16: Security Clearance Requirement
AR-17: Peer and Technical Reviews of Final Reports of Health Studies – ATSDR
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
AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
AR-34: Accessibility Provisions and Non-Discrimination Requirements
AR-36: Certificates of Confidentiality
AR-37: Prohibition on certain telecommunications and surveillance services or equipment for all awards issued on or after August 13, 2020.

Organization Specific ARs:
AR-8: Public Health System Reporting Requirements
AR-15: Proof of Non-profit Status
AR 23: Compliance with 45 C.F.R. Part 87

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75

To view brief descriptions of relevant CDC requirements visit: https://www.cdc.gov/grants/additionalrequirements/index.html

Additional CDC Award Requirements

The following Additional Requirements, some of which emphasize and expand upon those

above, will be required for all recipients funded under this NOFO.

All award recipients under this NOFO will be required to complete pre-registration of the research project(s) using publicly available platforms or ClinicalTrials.gov as applicable, consistent with the National Science Foundation's open science principles. The platform for intended pre-registration should be described in the Research Plan at the time of application.

All award recipients under this NOFO will be required to make data publicly available within 30 months of completing data collection, this includes making source code available to the public, and ensuring open access to research publications consistent with the National Science Foundation's open science principle.

The CDC will follow established implementation schedules and procedures for making grant awards under this NOFO in accordance with HHS and CDC Policy for Grant Program Administration and CDC Policy for Peer Review of Research and Scientific Programs to ensure that these awards support ideologically and politically unbiased research projects.

Data Management Plan. Applicants should develop and include, as part of the application's Resource Sharing Plan section of the PHS 398 Research Plan Component, a data management plan that meets the requirements of AR-25 using their own template. Applicants funded under this NOFO will be required to use NCIPC's Data Management Plan Template, OMB NO: 0920-1301 (Exp. Date: 06/30/2023) to make revisions to the DMP as required during the award's project period.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

• For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

• HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.

• For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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

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

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

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

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's

submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however, the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

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

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

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

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

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

Non-compliance with this Policy may result in suspension, limitation, restriction or

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

Data Management Plan(s)

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

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

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

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

4. Cooperative Agreement Terms and Conditions

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

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the recipients is anticipated during the

performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and HHS/CDC as defined below.

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

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Nonresearch Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html
- Designing and conducting research to address the described research objectives of this cooperative agreement.
- Undertaking any data collection solely to meet the applicant's research needs. Retaining custody of and exercising 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.
- Partnering effectively with any outside entities expected to participate in the proposed research. Such partnerships should be well-defined and documented by letters of support or Memoranda of Understanding detailing the nature and extent of involvement.
- Establishing goals and objectives that are realistic, measurable, and time- oriented for all phases of the project.
- Developing a research protocol involving human subjects for Institutional Review Board (IRB) review and approval by all cooperating institutions participating in the research project, including CDC if applicable.
- Assuring that IRB approvals are current for research involving human subjects for all participating sites.
- Considering suggestions from CDC on the design and implementation of research and the analysis, interpretation, and dissemination of study findings.
- Developing, designing, and piloting research protocols and instruments; recruiting participants; and conducting appropriate data management procedures.
- Analyzing data and disseminating findings in peer-reviewed journals and presentations at scientific conferences and other meetings.
- Requesting consultation and technical assistance from CDC, as needed. Considering suggestions from CDC on the design and implementation of research and the analysis, interpretation, and dissemination of study findings.
- Collaborating with CDC in translating and disseminating research findings.
- Participating in an initial kick-off meeting with CDC by phone or in Atlanta.
- Participating in one reverse site visit with CDC in Atlanta on an annual basis to review the project's progress with CDC scientists and staff.
- Developing and implementing a plan for sharing research resources and data with other collaborating partners, the agency, the public, and scientific community.

The PI is responsible for developing and updating a data management plan that identifies the level of data access and plans for data sharing.

CDC staff has substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below. CDC staff will work collaboratively with the PIs/PDs, as described below:

- Assist the PI, as needed, in complying with the investigator responsibilities described in the Policy on Public Health Research and Non-research Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html
- Provide suggestions for refining research protocols (e.g., for sampling, recruitment, assessment, and data management).
- Participate in the analysis, interpretation, and dissemination of study findings (may include co-authorship of peer-reviewed manuscripts and scientific presentations). CDC will not initiate or direct data collection, own or manage the data, require the use of a specific methodological approach, or disseminate findings as part of an official CDC report. Monitoring and evaluating the scientific and operational accomplishments of the project through conference calls, site visits, and review of technical reports. Provide ongoing suggestions as needed to ensure project success.
- Collaborate with the grant recipient to ensure human subjects assurances are in place as needed.
- As necessary, collaborate in the development or amendment of a research protocol involving human subjects for Institutional Review Board (IRB) review by all collaborating institutions, including CDC if applicable.
- Obtain IRB approvals as required by CDC when CDC is engaged in research involving human subjects. If applicable, the CDC IRB will review the protocol initially and on an annual basis until the project is complete.
- Monitor and evaluate the scientific and operational accomplishments of the project through conference calls, site visits, and review of technical reports.
- Provide ongoing suggestions as needed to ensure project success.
- The agency Scientific Program Official (SPO) and CIO program director will be responsible for the normal scientific and programmatic stewardship of the award. The SPO will be named in the award notice.

Areas of Joint Responsibility include:

- The grant recipient and CDC will agree upon and establish a schedule for regular phone calls to discuss ongoing research project progress.

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).

Technical Review and Summary Statement Response Requirements
Recipients will be required to electronically submit a response to the peer reviewers' comments and/or concerns, as documented in the Summary Statement, within 30 days of the notification of their initial award. Recipients will also be required to electronically submit a response to any progress concerns or areas for improvement noted on their annual Technical Review within the time period specified in the annual award continuation notice.

Annual Report Requirements
Recipients will be required to electronically submit an Annual Report within 90 to 120 days before the end of the current budget period. The Annual Report should include:

- A description of the completion status of each Specific Aim and/or research objective or milestone for the budget period.
- A complete list of the publications planned or completed to date - including status (e.g., published [include reference], in review, under development).
- A description of any changes made in the use of human subjects or IRB approval status.

- A description of any changes made in the Data Management Plan. Award recipients funded under this NOFO will be required to use NCIPC's Data Management Plan Template, OMB NO: 0920-1301 (Exp. Date: 06/30/2023) to make revisions to the DMP as required during the award's project period.

A. Submission of Reports

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

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

B. Content of Reports

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Additional Reporting Requirements:

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

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

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

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

FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For

further information, contact GrantsInfo@nih.gov. Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.

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

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

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

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

stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

6. Termination

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

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

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

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

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

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

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

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

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

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

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or

more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:

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

"Foreign government" includes any foreign government entity;

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

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

5) Contents of Reports: The reports must contain:

a. recipient name;

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

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

d. reporting period;

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

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

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

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

Section VII. Agency Contacts

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

Application Submission Contacts

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

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

Scientific/Research Contact
Susan Neurath, PhD
National Center for Injury Prevention and Control (NCIPC)
Telephone: 770.488.3368
Email: SNeurath@cdc.gov

Peer Review Contact
Mikel Walters, Ph.D.
National Center for Injury Prevention and Control (NCIPC)
Telephone: 404.639.0913
Email: MWalters@cdc.gov

Financial/Grant Management Contact(s)
Manal Ali
Grants Management Specialist
CDC Office of Grants Services
Telephone: 770.488.2706
Email: MAli@cdc.gov

Section VIII. Other Information

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

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

Authority and Regulations

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

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

Successful recipients may be permitted expanded authorities in the administration of this award as provided for in the Code of Federal Regulations, Title 2, Subtitle A, Chapter II, Part 200, Subpart D, §200.308(d)(4). Specific authorities granted will be detailed in the official Notice of Award document.

Application Submission Process

Applications must be successfully submitted and complete all validation actions prior to 5PM ET of the application due date for this NOFO. Applicants are encouraged to submit the application in ASSIST three (3) business days before the stated due date to provide sufficient time to correct any errors. If post-submission errors are identified during the validation process, the errors must be corrected and the application must be re-submitted in ASSIST prior to 5PM ET of the application due date. 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.

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk and the Grants.gov Contact Center. See *Section IV. Application and Submission Information, 9 Submission Dates & Times* for contact information.

General Information
All applications submitted for this NOFO must be responsive to the specific requirements and objectives of this NOFO and must be submitted as a new application through www.grants.gov.

All applicants are advised to carefully review the responsiveness requirements and instructions on how applicants must document responsiveness in *Section III. Eligibility Information 5. Responsiveness* of this NOFO.

Applicants are encouraged to pay close attention to the Data Management Plan requirements listed in the NOFO and to keep these in mind while preparing their proposals.