



**U.S. Department of
Health and Human Services**
Centers for Disease
Control and Prevention

Print Date: 11/15/22

Title: HEADS UP Outreach to At Risks Groups--Formative Testing

Project Id: 0900f3eb81fd36c0

Accession #: NCIPC-TBIT-9/13/22-d36c0

Project Contact: Kelly Sarmiento

Organization: NCIPC/DIP/ASB/TBIT

Status: **Project In Progress**

Intended Use: **Project Determination**

Estimated Start Date: 01/02/2023

Estimated Completion Date: 05/31/2023

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: 0920-1154

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research / Other <i>45 CFR 46.102(l)</i> Other - Formative research for message testing - Nonhuman subjects as defined per regulations will be involved.	10/31/22	Angel_Karen C. (idy6) CIO HSC

PRA: PRA Applies		10/31/22	Angel_Karen C. (idy6) OMB / PRA
ICRO: PRA Applies	OMB Approval date: 1/21/20 OMB Expiration date: 1/31/23	10/31/22	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Date Needed: 10/31/2022

Determination Start Date: 09/13/22

Description:

HEADS UP is a series of educational initiatives, developed by CDC, that all have a common goal: to help protect children and teens from concussions and their potentially devastating effects. Some groups are disproportionately affected by concussions and other traumatic brain injuries (TBIs). For example, American Indians/Alaska Natives have higher rates of TBI than other groups. A recent CDC report found that Black and Hispanic high school students were more likely to report having had multiple sports- or physical activity-related concussions during the preceding 12 months than non-Hispanic White high school students. Prior research points to less access to non-contact sport options, socioeconomic factors and less concussion awareness and access to concussion education as potential explanations for higher rates of concussions among Black and Hispanic youth as compared to non-Hispanic White youth. Currently, health communication messaging in the HEADS UP initiative, as well as other external concussion educational efforts, are designed to reach a broad audience of youth and parents. Existing messages and materials have never been tested to assess differences in their effectiveness by race/ethnicity, sex, socioeconomic status, and place of residence (rural versus urban areas). As such, the objective of this activity is to understand barriers and opportunities to improve outreach of HEADS UP materials and messages to study participants and the best approaches to reaching them with information.

IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:

No

IMS Activation Name:

Not selected

Primary Priority of the Project:

Not selected

Secondary Priority(s) of the Project:

Not selected

Task Force Associated with the Response:

Not selected

CIO Emergency Response Name:

Not selected

Epi-Aid Name:

Not selected

Lab-Aid Name:

Not selected

Assessment of Chemical Exposure Name:

Not selected

This projects seeks to conduct formative research (including a literature review and focus group discussions) to inform the

Goals/Purpose	development and dissemination of messages and materials about concussions to Black/African American, Latino/Hispanic, and American Indian/Alaska Native youth and their parents, as well as to identify and test messages that resonate with the target audiences.
Objective:	<p>The purpose of the literature review is to conduct exploratory research to: ? Gain a greater understanding of Black/African American, Latino/Hispanic, and American Indian/Alaska Native youths#: ? Concussion/traumatic brain injury (TBI) knowledge ? High-risk concussion behaviors ? Help-seeking norms ? Barriers to seeking care ? Gain a greater understanding of Black, Latino, and American Indian/Alaska Native parents#: ? Concussion/TBI knowledge ? Care-seeking norms ? Barriers to seeking care ? Understand current social norms around: ? High-risk concussion behaviors ? Injury help-seeking ? Gather information on any existing concussion prevention communications campaigns other than CDC's HEADS UP The purpose of the focus group discussions is to conduct further exploratory research to: ? Identify barriers of Black/African American, Latino/Hispanic, and American Indian/Alaska Native youth to engaging in concussion prevention behaviors in sports, as well as opportunities to improve their likelihood of engaging in concussion prevention behaviors in sports ? Understand concussion help-seeking behaviors of Black /African American, Latino/Hispanic, and American Indian/Alaska Native youth, including barriers to help-seeking and opportunities to increase concussion help-seeking behaviors ? Identify barriers and opportunities to improve outreach of HEADS UP materials and messages to study participants and the best approaches to reaching them with information ? Identify messages and materials that resonate with Black/African American, Latino/Hispanic, and American Indian/Alaska Native youth and parents and that will increase their concussion prevention and help-seeking behaviors in sports</p>
Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:	Yes
Project does not incorporate elements of health equity science:	Not Selected
Measuring Disparities:	Not Selected
Studying Social Determinants of Health (SDOH):	Not Selected
Assessing Impact:	Not Selected
Methods to Improve Health Equity Research and Practice:	Yes
Other:	This projects seeks to conduct formative research (including a literature review and focus group discussions) to inform the development and dissemination of messages and materials about concussions to Black/African American, Latino/Hispanic, and American Indian/Alaska Native youth and their parents, as well as to identify and test messages that resonate with the target audiences.
Activities or Tasks:	Research with Humans
Target Populations to be Included/Represented:	Children ; American Indian or Alaska Native ; Black or African American ; Hispanic or Latino
Tags/Keywords:	Brain ; Brain Concussion ; Brain Injury, Chronic
CDC's Role:	Activity originated and designed by non-CDC staff (awardee or external collaborator)
Method Categories:	Discussion Group
	DIP has contracted with Banyan Communications. Banyan will conduct the literature review using an approach, search terms and

Methods:

search parameters developed in collaboration with and agreed upon by DIP. Banyan will deliver an interim report detailing the findings of the literature review. Banyan will propose questions for the focus groups (FG) to better understand facilitators and barriers to concussion prevention behaviors. Banyan will then conduct up to seven focus group discussions (FGD) with 6-8 participants in each FG. Banyan will recruit parents and youth who are African American/Black, Latino/Hispanic, and American Indian/Alaska Native or via a market research company and will recruit up to 10 participants per FG to account for attrition. Participants will be screened based on inclusion/exclusion criteria set by CDC and asked to provide informed consent prior to participating in the FGs. Consent forms will include instructions for only using first names during interviews to protect confidentiality and privacy. FGDs will be approximately 60 minutes in length. They will be conducted via Zoom at times convenient for participants and scheduled to allow participation from multiple time zones to ensure regional variation within the groups. The FGDs will be conducted by a skilled facilitator supported by a note-taker and FG coordinator responsible for taking observational notes, managing the chat function on Zoom, and troubleshooting the technology. The note-taker will use a note-taking template based on the semi-structured discussion guide, but the FGDs will also be recorded. Banyan will repeat the FG methodological process following the formative research and communications messaging and materials development in order to test messages and materials with the up to seven target audiences.

Collection of Info, Data or Biospecimen:

At most 7 focus group discussions (FGDs) for formative research and at most 7 FGDs for message testing will take place during online meetings via Zoom. Focus groups (FGs) will include up to 8 participants each. The FGDs will be recorded with an observer /notetaker present. For formative research, a guide will be used to collect information on concussion knowledge, attitudes, and beliefs; health-seeking behaviors (concussion and general health issues); barriers to seeking care (concussion and general health issues); trusted sources of information; and health reporting behaviors. For message testing, draft messages and materials will be shown and a guide will be used to assess their comprehensibility; ability to improve knowledge; acceptability; engagement; and motivational capacity to engage in proper care of concussions. Data analysis and reporting: Following completion of formative research FGDs, the contractor will review FGD recordings and compile a summary of findings to inform message and material development. Following completion of message testing FGDs, the contractor will review FGD recordings and compile a summary of findings to inform updates to the CDC HEADS UP messages and materials.

Expected Use of Findings/Results and their impact: Findings will be used to inform the development of CDC HEADS UP messaging and materials.

Could Individuals potentially be identified based on Information Collected? No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Contract	HEADS UP Outreach to At Risks Groups		2022	3	

HSC Review

HSC Attributes

Other - Formative research for message testing - Nonhuman subjects as defined per regulations will be involved. Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office No

Estimated number of study participants

Population - Children

Protocol Page #:

Population - Minors

Protocol Page #:

Population - Prisoners

Protocol Page #:

Population - Pregnant Women

Protocol Page #:

Population - Emancipated Minors

Protocol Page #:

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

Requested consent process wavers

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Alteration of authorization under HIPPA Privacy Rule No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those tested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identifiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
Banyan Communications	FWA00029147	01/07/25	Sterling Institutional Review Board IRB #1 - IRBs 3-7	08/10/24	

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Jill Daugherty	12/27/2024		09/20/2024		Technical Monitor	xdu1@cdc.gov	404-498-1830	TRAUMATIC BRAIN INJURY TEAM
Kelly Sarmiento	07/27/2025		09/27/2024		Technical Monitor	egz8@cdc.gov	770-488-1384	TRAUMATIC BRAIN INJURY TEAM

Data

DMP

Proposed Data Collection Start Date: 11/15/22

Proposed Data Collection End Date: 7/15/24

Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - Data will only be used for internal program evaluation

Public Access Justification: The data will be used to inform revisions of CDC communications materials. Information will be limited to focus group respondents and will be deidentified. Communications materials will be refined following qualitative data analysis.

How Access Will Be Provided for Data: Data will not be released to the public.

Plans for Archival and Long Term Preservation: Data will be destroyed upon project completion.

Spatiality

Spatiality (Geographic Locations) yet to be added

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	10/31/2022	NOA 0920-1154 (2020)	Notice of Action	NOA 0920-1154.pdf
Current	Sarmiento_Kelly (egz8) Project Contact	09/13/2022	Literature review plan	Other-Enter new type	HU At Risk_Lit Review Plan.docx



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