



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

Print Date: 1/6/23

Title: Assessing Knowledge, Attitudes, and Practices (KAPs) of Hispanic or Latina Women of Reproductive Age About Folic Acid Fortification and Supplementation

Project Id: 0900f3eb81f07cff

Accession #: NCBDDD-HCRT-4/21/22-fc4f7

Project Contact: Jasmine R Owens

Organization: NCBDDD/DBDID/IOMRP/HCRT

Status: Pending Regulatory Clearance

Intended Use: Project Determination

Estimated Start Date: 09/29/2022

Estimated Completion Date: 09/28/2024

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #:

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Non-Exempt Human Subjects Research when CDC is not engaged <i>45 CFR 46.102(a) HHS/OHRP 2008 Engagement Guidance at III B(1-11)</i>	4/26/22	Campbell_Scott (sic3) CIO HSC
PRA: PRA Applies		4/27/22	Herron_Adrienne R. (xwj9) OMB / PRA

Description & Funding

Description

Priority: Standard

Date Needed: 05/11/2022

Determination Start Date: 04/27/22

Description: Consuming 400 micrograms (mcg) of folic acid daily in the periconceptional period can reduce the risk of having a pregnancy affected by a neural tube defect (NTD), a severe birth defect of the brain and spine. To increase the amount of folic acid consumed in the U.S. population, the U.S. Food and Drug Administration (FDA) mandated fortification of enriched cereal grain products with folic acid in 1998. Although strides have been made in preventing neural tube defects, ethnic disparities remain. Hispanic women in the U.S. have the highest risk of having a child affected by a NTD, with birth prevalence of approximately 7 NTDs per 10,000 live births. In addition, Hispanic women: # Have lower levels of folate in their blood compared to non-Hispanic white women; # Are more likely than non-Hispanic white and non-Hispanic black women to have the MTHFR C677T gene variant; # Are less likely to know about the benefits of folic acid; # Are less likely to get folic acid from fortified foods or take a multivitamin with folic acid in it, particularly those women who primarily speak Spanish, were born outside of the United States, and have lived in the United States for a shorter period of time. A contract proposal has been submitted to enlist services for health marketing and communications through the Office of the Associate Director for Communication's Blanket Purchase Agreement (BPA). The purpose of this contract is to conduct formative research with Hispanic/Latina women of reproductive age through organizations who are engaged with the population to examine folic acid and fortified food awareness, food and supplement use practices, as well as messaging and channels to reach Hispanic/Latina women. Formative research will involve the contractor conducting focus groups with Hispanic /Latina women and semi-structured interviews with leaders from key organizations serving Hispanic populations.

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

Goals/Purpose The purpose of the contract will be to conduct formative research with Hispanic/Latina women of reproductive age through organizations who are engaged with the population to examine folic acid and fortified food awareness, food and supplement use practices, as well as messaging and channels to reach Hispanic/Latina women.

The objectives for the project include 1) conduct formative research (i.e., focus groups and semi-structured interviews) contracted

Objective:	through national or community-based organizations to examine folic acid and fortified food knowledge and awareness, food and supplement use practices, as well as messaging and channels to reach Hispanic women and 2) target Hispanic communities to recruit women for focus groups with regard to the size of the Hispanic community overall and by women of reproductive age, as well as the composition of Hispanics by country of origin.
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:	Not Selected
Other:	Formative research will be conducted to understand knowledge, attitudes, and practices related to folic acid fortification and supplementation among Hispanic/Latina women of reproductive age.
Activities or Tasks:	Programmatic Work
Target Populations to be Included/Represented:	Hispanic or Latino ; Female
Tags/Keywords:	Formative Feedback ; Health Communication ; Health Equity
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided
Method Categories:	Focus Group; Individual Interviews (Qualitative)
Methods:	A Request For Quote (RFQ) developed under the Office of the Associate Director for Communication's Blanket Purchase Agreement (BPA) mechanism will outline the final deliverables required from this contract. The vendor would propose communication formative research methods for collecting data on knowledge, attitudes, and practices of Hispanic/Latina women of reproductive age. This might include approximately 9-12 focus groups with Hispanic women of reproductive age and 7-9 semi-structured interviews with leaders from key organizations servicing Hispanic populations to gather qualitative data. The total number of focus groups and interviews that will be conducted will be finalized with the vendor based on final project timelines. The vendor will propose a research plan (including formative research approach, focus group and interview guides, and others deemed appropriate for the population) that will serve as the basis for an OMB clearance package.
Collection of Info, Data or Biospecimen:	The qualitative data will be collected through the vendor via focus groups and semi-structured interviews. Responses from the qualitative efforts (e.g., focus groups and semi-structured interviews) will be summarized by the vendor and no personally identifiable information will be shared with CDC. The specific instruments that will be developed for collecting the data will be determined after the contract has been awarded. The results from the focus groups and semi-structured interviews that will be conducted under this contract are expected to be used for developing new messaging and communication products to improve knowledge, awareness, and practices regarding folic acid

Expected Use of Findings/Results and their impact: fortification and supplementation among Hispanic/Latina women of reproductive age. Additionally, the findings from the project will inform future intervention activities to prevent neural tube defects among Hispanic women of reproductive age.

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	Assessing Knowledge, Attitudes, and Practices (KAPs) of Hispanic/Latina Women of Reproductive Age About Folic Acid Fortification and Supplementation	RFQ # 2022-031	2022	2	200000.00

HSC Review

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 bested 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

Institutions yet to be added

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
Cara Mai	12/18/2025	03/26/2022	05/11/2021		Technical Monitor		404-498-3918	NEURAL TUBE DEFECTS SURVEILLANCE & PREVENTION TEAM
Jasmine Owens	12/09/2025				Technical Monitor		404-498-0236	HEALTH COMMUNICATION AND RESEARCH TRANSLATION
Kara Polen	12/05/2025		08/06/2025		Technical Monitor		404-498-3914	HEALTH COMMUNICATION AND RESEARCH TRANSLATION

Data

DMP

Proposed Data Collection Start Date: 9/29/22
Proposed Data Collection End Date: 9/28/24
Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - Formative research findings will be used to inform messaging and communication products that will be developed by CDC.

Public Access Justification: The data that will be collected are qualitative and will not generate a data set for use by the public. In addition, the qualitative data could result in information that is identifiable, although it will be de-identified when shared back with CDC.

How Access Will Be Provided for Data: Data collected from the contractor will not include personal identifiers when shared with CDC. Please see above regarding why public access will not be provided. CDC will work with the vendor to determine the best methods for storing the qualitative data that are collected, before sharing it with CDC.

Plans for Archival and Long Term Preservation:

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

No Supporting Info



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