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

Print Date: 6/17/22

Title: Youth and Young Adult Formative In-Depth Interviews on Health Equity and Tobacco Use

Project Id: 0900f3eb81ee9d75

Accession #: NCCDPHP-RDT-4/12/22-e9d75

Project Contact: Christina V Watson

Organization: NCCDPHP/OSH/E/RDT

Status: **Pending Regulatory Clearance**

Intended Use: **Project Determination**

Estimated Start Date: 09/28/2022

Estimated Completion Date: 09/27/2023

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 *45 CFR 46.102(a) HHS/OHRP 2008 Engagement Guidance at III B(1-11)*	5/11/22	Redmond Leonard_Joan (jrl3) CIO HSC
PRA: **PRA Applies**		5/12/22	Still-LeMelle_Terri (cse6) OMB / PRA

Description & Funding

Description

Priority:	Standard
Determination Start Date:	04/13/22
Description:	This project will conduct 60 in depth interviews (IDIs) with youth ages 12-17 and young adults ages 18-25 to better understand the relationship between health equity and social determinants of health on tobacco use and cessation. Tobacco use is the leading cause of preventable disease, disability, and death in the United States, and it primarily starts during adolescence. Additionally, persistent disparities in tobacco use exist among racial and ethnic groups, sexual minorities, people of low socioeconomic status, and other vulnerable populations. These disparities are further driven by a complex web of influencers such as social determinants of health. Project activities will include screening, administering consent forms, conducting 30 interviews with youth ages 12-17 and 30 interviews with young adults ages 18-25, distributing incentives, and analyzing data. The information is intended to help improve surveillance and support the development of metrics and constructs related to health equity, particularly among vulnerable population, that can be included in future surveys such as the NYTS and BRFSS. CDC staff will not be engaged in data collection. Results will not be generalized to a broader audience.
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	This project will conduct 60 in depth interviews (IDIs) with youth ages 12-17 and young adults ages 18-25 to better understand the relationship between health equity and social determinants of health on tobacco use and cessation. Tobacco use is the leading cause of preventable disease, disability, and death in the United States, and it primarily starts during adolescence. Additionally, persistent disparities in tobacco use exist among racial and ethnic groups, sexual minorities, people of low socioeconomic status, and other vulnerable populations. These disparities are further driven by a complex web of influencers such as social determinants of health. Project activities will include screening, administering consent forms, conducting 30 interviews with youth ages 12-17 and 30 interviews with young adults ages 18-25, distributing incentives, and analyzing data. The information is intended to help improve surveillance and support the development of metrics and constructs related to health equity, particularly among vulnerable population, that can be included in future surveys such as the NYTS and BRFSS. CDC staff will not be engaged in data collection. Results will not be generalized to a broader audience. The purpose of this project is to conduct individual formative interviews with youth (ages 12-17) and young adults (ages 18-25) to

Objective:	better understand issues related to health equity and its influence on tobacco use and cessation. The goals are to identify health equity constructs and the social determinants of health that may be related to tobacco use and cessation as well as barriers to accessing cessation. This information will be crucial in addressing the underlying factors and systematic influencers that are contributing to tobacco use in youth. The specific objective of the project is to gather in depth information from youth and young adults on tobacco knowledge, attitudes, usage and cessation as it relates to health equity. More specifically, the objectives are to better understand the significance of individual (e.g., behaviors), interpersonal (e.g., health and language literacy, educational attainment, media influences), community (e.g., neighborhood safety, housing, and tobacco exposure), and societal (e.g., discrimination) experiences and influences. This information will help inform surveillance and enable CDC to better identify underlying and systemic factors that may inform future survey and tools and programs or activities (message development, education campaigns) for tobacco prevention and cessation among youth and young adults. CDC's contractor will work with professional recruiting firms to screen and recruit for eligible participants. CDC staff will not be engaged in data collection.
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?:	No
Project does not incorporate elements of health equity science:	Not Selected
Measuring Disparities:	Not Selected
Studying Social Determinants of Health (SDOH):	Yes
SDOH Economic Stability:	Yes
SDOH Education:	Yes
SDOH Health Care Access:	Yes
SDOH Neighborhood and Environment:	Yes
SDOH Social and Community Context:	Yes
SDOH Indices:	individual (e.g., behaviors), interpersonal (e.g., health and language literacy, educational attainment, media influences), community (e.g., neighborhood safety, housing, and tobacco exposure), and societal (e.g., discrimination) experiences and influences.
Other SDOH Topics:	Not Selected
Assessing Impact:	Not Selected
Methods to Improve Health Equity Research and Practice:	Not Selected
Other:	Not Selected
Activities or Tasks:	Programmatic Work
Target Populations to be Included/Represented:	Children
Tags/Keywords:	Tobacco
CDC's Role:	Activity originated and designed by non-CDC staff (awardee or external collaborator)

Method Categories:	Individual Interviews (Qualitative)
Methods:	A CDC contractor will conduct 60 formative in depth interviews approximately 60 minutes in length with youth aged 12 to 17 years and young adults aged 18 to 25 years. We propose conducting 30 interviews per age segment. While age is the only predefined segment for this, we will strive to achieve a diverse sample of youth by such factors as tobacco use status (e.g., non-user, current user, former user, type of tobacco product used), race/ethnicity, sexual orientation/gender identity, socioeconomic status, geography (i.e., rural, urban), U.S Census region (i.e., Northeast, South, West, Midwest), and/or other relevant factors. We will employ a purposive sampling strategy working with two recruitment firms through a two-stage approach. Stage 1 involves recruiting youth and young adults from the nationwide web panel MFour Surveys on the Go#. Youth ages 12 to 17 years will be recruited through adult panelists who have children in their household (which is characteristic included in the panel profile). These parents /guardians will be prompted to complete a screener survey, which will identify those with children aged 12-17. Parents with children aged 12 to 17 who are deemed eligible will then be sent further information, as well as a form to obtain consent for their child to participate. After obtaining parental consent, children will then be asked to complete a youth screener survey so that the contractor can obtain additional relevant information. The contractor will draw on this information when selecting youth to invite to participate. Youth who are selected will be sent a assent form to complete prior to participation. Young adult participants (18-25 years old) will also be recruited through the recruitment firm#s panel and will be asked to complete a similar survey. Young adults who are selected will also be sent a assent form to complete prior to participation. To address gaps in age groups or other segments not found using MFour, contractor will initiate Stage 2 of the recruitment strategy. This next step will include working with another recruitment firm, Research America, to address any gaps in recruitment. The contractor has worked extensively with Research America on several previous projects to successfully recruit hard-to-reach populations including youth, ethnic minority populations, and people who use drugs. Research America uses a national panel to recruit participants, and conducts extensive outreach with national, regional, and local organizations to supplement their efforts to support specific outreach efforts. The contractor will again obtain parental consent, conduct a short youth screener, and obtain consent from all participants identified through Research America. Young adult participants (18-25 years old) will also be recruited through this second recruitment firm, asked to complete a short screener, and obtain consent. After completing the interviews, the contractor will prepare transcripts from the recordings and conduct qualitative data analysis to identify common themes and outliers. We will be requesting OMB approval, via the existing Generic Clearance for CDC/ATSDR Formative Research and Tool Development (0920-1154), which supports formative research for the development or improvement of interventions and tools for CDC/ATSDR via qualitative in-depth interviews among consumers.
Collection of Info, Data or Biospecimen:	CDC contractor will recruit youth and obtain parental consent and youth consent for the virtual interviews. The contractor will use both a nationwide web panel and a professional recruitment firm to recruit eligible interview participants using an approved screener. The contractor will have access to some PII from participants and their parents, including first and last name, phone numbers, and email addresses. The contractor will also know participants# grade level, sex, and race and ethnicity. Each participant will be assigned a project ID, and the ID will be used on all subsequent notes, transcripts, and audio recordings with the project ID. The interviews will be conducted virtually. CDC will not be engaged in data collection. The contractor will audio record the interviews, take notes, create transcripts, and share de-identified audio recordings and transcripts with CDC. CDC will not receive any PII data from participants. ICF will take several steps to safeguard the audio recordings. Recordings will be saved on a project-specific drive with restricted access. Only members of the project team or a designated member of the contractor#s IT staff will be able to access the folder with the recordings. Contractor staff will delete local copies of the recordings as soon as they are uploaded onto the secure server. Participants will not be referred to by name in any report or communications. Finally, when transferring any project data to CDC, the contractor will use their secure file transfer protocol (SFTP) server. Transfers to and from the SFTP server are protected by data encryption. The SFTP server meets all government security requirements, including the FIPS 140-2 encryption standard.
Expected Use of Findings/Results and their impact:	Project findings will help CDC to better identify underlying and systemic factors that relate to tobacco use and cessation among youth and young adults to improve surveillance and support the development of metrics and constructs related to health equity, particularly among vulnerable population. This project is intended as public health practice and not research since the goal is not to

create generalizable knowledge, but rather to formatively explore youth and young adults# knowledge, attitudes, usage and cessation as it relates to issues of health equity in order to inform OSH#s surveillance and programmatic activities.

Could Individuals potentially be identified based on Information Collected? No

Funding

Funding yet to be added .....

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 waviers

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 identfiable 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
Alexander Schwank	06/17/2024				Co-Investigator		- -	RESEARCH DEVELOPMENT TEAM
Katrina Trivers	01/31/2023		04/10/2023		Principal Investigator		404-498-6861	EPIDEMIOLOGY BRANCH

Data

DMP

Proposed Data Collection Start Date:	9/28/22
Proposed Data Collection End Date:	9/20/23
Proposed Public Access Level:	Non-Public

Non-Public Details:

Reason For Not Releasing Data:	Other - Not public health data
Public Access Justification:	Data is formative and will be utilized for internal purposes including survey development.
How Access Will Be Provided for Data:	All documents produced and/or collected before, during, and after each interview (e.g., screener data, audio files, interview notes, transcripts) will be stored in password-protected electronic files accessible only to contractor team members. Data files will be stored on a secure drive by respondent ID, a five-digit code used to track all data collection. Respondent names, or other identifiers, will never be used other than to coordinate data collection. The separate, task specific, secure drive will only be available to a limited number of project staff working on the analysis. The data storage #system# consists of the contractor#s corporate laptops of those individuals authorized to work on the data collection (estimated to be 3-5 individuals), and a secure shared drive. Each laptop is its own boundary and requires 2-factor authentication to log in. De-identified response data will be captured to MS Office documents and then uploaded to NVivo for analysis. Microsoft Teams will be used to capture audio recording of interviews. Data sharing between team members within the contractor#s staff will happen via the secure folder, as will delivery of de-identified results to the CDC when done. All list data, response data, and audio recordings will be wiped from the laptops at the conclusion of the project using drive-wipe software with multiple passes. At the conclusion of the project, analyzed and deidentified data (audio files and transcripts) will be delivered (disassociated from any PII) to CDC. Data will subsequently be scrubbed from all files. All laws, regulations, and rights regarding data will be applied.
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

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info

	Watson_Christina (bsu8) Project Contact	05/04/2022	Attachment 1	Other	1154 OSH Qual Att 1_Public Health Service Act_42 USC 241.pdf
	Watson_Christina (bsu8) Project Contact	05/04/2022	Attachment 4	Other	1154 OSH Qual Att 4_Youth 12-17_Recruitment_Screener_Questionnaire.docx
	Watson_Christina (bsu8) Project Contact	05/04/2022	Attachment 3	Other	1154 OSH Qual Att 3_Parent_Guardian_Recruitment_Screener_Questionnaire.docx
	Watson_Christina (bsu8) Project Contact	05/04/2022	Attachment 2	Other	1154 OSH Qual Att 2_IRB_Application.docx
	Watson_Christina (bsu8) Project Contact	05/04/2022	Attachment 5	Other	1154 OSH Qual Att 5_Young Adult_Recruitment_Screener.docx
	Watson_Christina (bsu8) Project Contact	05/04/2022	Attachment 9	Other	1154 OSH Qual Att 9_ Interview_Moderator_Guide.docx
	Watson_Christina (bsu8) Project Contact	05/04/2022	Attachment 8	Other	1154 OSH Qual Att 8_Young Adult_Informed_Consent.docx
	Watson_Christina (bsu8) Project Contact	05/04/2022	Attachment 7	Other	1154 OSH Qual Att 7_Parent_Email_Youth12-17_Informed_Assent.docx
	Watson_Christina (bsu8) Project Contact	05/04/2022	Attachment 6	Other	1154 OSH Qual Att 6_ParentGuardian_Email_Informed_Consent.docx
Current	Watson_Christina (bsu8) Project Contact	05/02/2022	Protocol	Protocol	OSH Qualitative Inquiry_Deliverable 3.1 _Protocol_05022022.docx
	Watson_Christina (bsu8) Project Reviewer	04/22/2022	Track changes	Other	STARS form response to Dave 4.22.22.docx

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