GenIC Clearance for CDC/ATSDR
Formative Research and Tool Development

Youth Audience Message Testing of Substance Use Prevention Messages

Supporting Statement A

Contact: Jasmine Kenney, MPH
Communication Branch
Division of Overdose Prevention (DOP)
National Center for Injury Prevention and Control (NCIPC)
Centers for Disease Control and Prevention (CDC)
4770 Buford Hwy NE, MS S106
Atlanta, Georgia 30341

Phone: 770-488-5423
Email: gnk2@cdc.gov

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A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) National Center for Injury Prevention and Control (NCIPC), Division of Overdose Prevention (DOP) is seeking to develop a youth-focused campaign to communicate the mental/behavioral health impacts and risk awareness and outcomes related to substance use, overdose, and addiction.

In the United States, drug overdoses have claimed over 1 million lives since 1999, and the drug overdose crisis continues to worsen. In 2021, a total of 106,699 drug overdose deaths occurred, and the rate of drug overdose deaths increased by 14% from the year before.[1] Synthetic opioids, such as illegally made fentanyl, continue to contribute to the vast majority (nearly 88%) of opioid-involved overdose deaths.[2] The median rate of monthly overdose deaths among adolescents (ages 10 to 19) increased by 109% from July–December 2019 to July–December 2021.[3] Adolescent deaths related to illegally made fentanyl increased by 182% during the same period. Notably, about 41% of decedents were likely experiencing mental health conditions.[3]

Audience testing is a best practice for developing relevant, effective, and impactful health messages and campaigns. In the current research effort, we will conduct an asynchronous qualitative online panel study to test proposed campaign messages and concepts with youth audiences ages 13 to 17. The focus areas of the campaign messages will include drug use and overdose risk awareness and outcome and mental/behavioral health impacts.

Overview of the Data Collection System

We will collect qualitative data, using online panel discussions (interviews) through a recruitment and market research vendor, YPulse, which uses national panels of youth participants to recruit a non-probability sample from relevant markets.

Potential participants will first complete a screener by phone with a recruiter (**Attachment 1**). For each participant who qualifies and agrees to participate, the recruiter will review the consent information with parents (20 mins) (**Attachment 2**), then the assent form with each youth participant (20 mins) (**Attachment 3**) and answer any questions they have.

The vendor will use four online activities to collect data from youth ages 13–17. Each of the four online data collection activities will last about 45 minutes, with an additional estimated 10 minutes per participant for follow-up activities. The total data collection time for each participant is up to 3 hours and 10 minutes. Participants will have up to 2 weeks to complete the activities and submit their answers.

CDC developed an activity guide that will facilitate data collection during the panel discussion (see **Attachment 4**). The activity/moderator guide will contain all instructions, prompts, questions, probes, tasks, and stimuli (e.g., written messages, graphic concepts) that respondents will read and review. A moderator will support participants by facilitating participation in the discussion, reviewing responses to

encourage completeness or responses, answering questions, and troubleshooting technical issues. Respondents can review as often as needed while answering the questions.

Respondents will access all activities through a private, secure online platform provided by the vendor (see **Attachment 5**). For each activity, respondents will be shown the tasks as written based on the materials guide. Participants will be notified of a deadline date and time for when an activity closes. The activities will be asynchronous, meaning that participants can complete them at their own pace whenever it is most convenient for them (e.g., evenings, weekends), and they can take as much time as needed in the established 2-week timeframe. Participants will receive multiple reminders about deadlines and tasks to complete on a regular basis (a few times a week and more frequently, including generally daily, within the last week of the final deadline).

Moderators will probe participants' answers to obtain more detailed responses as needed. Data collection activities will include opportunities for participants to submit their answers privately (without other participants seeing them) and to select discussion opportunities for which participants can read others' responses and interact with each other.

Information to Be Collected

For each activity, respondents will be given a series of items (i.e., tasks) to read and respond to. Each activity will be made up of approximately 20 to 24 tasks. Tasks will collect information relate to knowledge, attitudes, behaviors about substance use and mental health, and perceptions of campaign concepts and messages related to substance use and mental health. Responses will consist of typed responses from each participants including short answer responses, results from selecting between two or more stimuli, a numeral ranking or Likert-response to stimuli, and other similar prompts. Example activities might include open-response questions, rating prompts, and ranking activities for the stimuli. Example stimuli include campaign posters, taglines, messages, and social media posts. No PII will be collected during this data collection effort.

Identification of Web Site(s) and Web Site Content Directed at Children under 13 Years of Age

This information collection does not involve websites or website content directed at children less than 13 years of age.

A.2 Purpose and Use of the Information Collection

The purpose of this data collection effort is to:

1. Develop research protocols and implement data collection in a manner that is consistent with best research practices for individuals ages 13 to 17, including ethics and data privacy;
2. Collect rich feedback from youth ages 13 to 17 on the draft messages and campaign concepts; and
3. Identify and analyze trends and themes in the feedback about the messages and concepts to develop insights and recommendations that will inform the development of a youth-focused campaign.

The information collected will be used to:

1. Inform the development of a youth-focused campaign centered on increasing awareness of risks and outcomes related to drug use, drug overdose, and mental health.

A.3 Use of Improved Information Technology and Burden Reduction

To reduce the burden of data collection on participants, technology will be used to collect data through an online platform where participants can respond asynchronously, at a time and place convenient to participants. Questions will be kept to a minimum required for the intended use of the data.

A.4 Efforts to Identify Duplication and Use of Similar Information

There are no other known federal generic collections that duplicate the project included in this request. Health messages developed by CDC are unique in their mix of the intended audience, health behavior, concept, and execution. We have scanned search engines, reviewed existing materials for this group (i.e., conducted environmental scans in January 2023 and October 2023), and reviewed existing published data to identify information that could facilitate message development prior to conducting any data collection.[4–7] Results found the need for more drug overdose prevention awareness and behavior change campaigns specifically for youth. Additionally, results identified few campaigns targeting mental health, and none prioritized the role of mental health in substance use among youth.

A.5 Impact on Small Businesses or Other Small Entities

This project does not have an impact on small businesses or other small entities.

A.6 Consequences of Collecting the Information Less Frequently

The activities involve a one-time collection of data over a 12-month period. Without gathering feedback from youth audience members, the campaign materials would not be created based on CDC's health communication best practice of testing communications products with actual audience members for dissemination. The resulting materials would not be as effective on the critical topic of drug overdose among youth audiences.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with regulation 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

Exhibit A.8.1. Outside Consultation

Name	Organizational Unit
Everett Long, PhD, Principal Researcher	Fors Marsh (contractor)
LeShaundra Cordier, Sr. Advisor	Fors Marsh (contractor)
Elise Bui, PhD, Sr. Analyst	Fors Marsh (contractor)

A.9 Explanation of Any Payment or Gift to Respondents

Incentives will be offered to participants in the study. Participants will receive incentives in the form of a digital gift card. This amount is considered appropriate for this level of participation and is not considered coercive. Participants will receive $50 for completing the phone screener and consent/assent forms and $50 for each of the four online facilitated discussion activities (in-depth qualitative data collection similar to an interview, 45 minutes each, for a total of 180 minutes or 3 hours), for a total incentive of $250.

We have proposed incentives based on vendor recommendations based on their experience and current industry trends. The incentives are developed with consideration of the total amount of participation hours, which include data collection from both parents/guardians and youth. Current market researchers have noted that sufficiently-high incentives are necessary to collect reliable, high-quality, and valid responses from participants and to increase data completeness.[8,9] Additional industry recommendations include providing higher incentives for studies involving sensitive subjects (e.g., drug use or addiction);[10] ensuring sufficient incentives when conducting data collection over multiple sessions; and achieving recruitment quotas or goals around increasing participation among diverse audiences, especially racially, economically diverse, and populations disproportionately impacted by the negative impacts of a public health issue (e.g., drug overdose disparities among youth populations).[11]

Multiple studies using a variety of data collection methodologies have shown that offering incentives increases participation rates.[12–15] Reviewed literature revealed the use of incentives can provide significant advantages to the government in terms of direct cost savings and improved data quality. It also should be noted that message testing is a marketing technique, and it is a standard practice among commercial market researchers to offer incentives as part of respondent recruitment. Previous experience has shown that lower incentive levels can lead to difficult recruitment within the timeframe available for the research, resulting in lower-than-desired participation numbers. In response to offering this incentive level, respondents are much more likely to honor their commitment to participating in the online panel. Lower incentive amounts could lead to inadequate participation, delayed results, and/or higher recruiting costs and burden to the public due to the need for additional screening.

A.10 Assurance of Privacy Provided to Respondents

In review of this application, it has been determined that the Privacy Act is not applicable. This submission has been reviewed by the NCIPC's Information Systems Security Officer, who has determined that the Privacy Act does not apply.(Attachment 7 and 7a)

During data collection, the recruiter will identify, screen, and recruit potential participants through a vendor who will keep participant information private. Participants and their parents will be advised of their privacy upon signing up for the study and providing consent. The form will contain information regarding privacy and confidentiality along with a valid OMB number and contact information in case participants have questions about their rights as a participant.

Findings will be reported in aggregate form and all data collected will be separated from participants' names. Aggregate data and any other project-related documents will be retained on secure servers. Any staff will be required to sign a privacy agreement prior to the start of the project (see **Attachment 7** for a copy of the privacy agreement). Only project staff members will have access to the servers via password-protected computers.

No PII will be collected during this data collection effort. During data collection activities, participants will only be identified by their first name and last initial, with no accompanying profile picture, to protect their privacy and to increase their comfort level with the discussion. None of the questions, prompts, or data elements in the activities will require participants to share information about themselves that is private or sensitive, although participants may share whatever they choose. All participants will be informed that all responses are voluntary, and they do not have to respond to any questions that they do not wish to answer. Any PII that participants provide in their responses will be scrubbed before reporting.

CDC's contractor will retain study responses on secure servers or in locked file cabinets; only project staff members will be able to access the servers via password-protected computers. Findings will be reported in aggregate form and all data collected will be separated from participants' names. All study responses will be destroyed three years after completion of the project. No identifiable information describing individual respondents will be included in the analyzed data and aggregate reports provided to CDC.

Data will be kept private to the extent allowed by law.

A.11 Justification for Sensitive Questions

There is minimal risk that questions related to drug use, addiction, and/or overdose may make respondents feel uncomfortable or cause some emotional discomfort. It is necessary to get feedback around these sensitive topics, as best practices in health communication show that to develop effective materials, they must be based on audience data. This study does not constitute human subjects research. However, due to the inclusion of a vulnerable population (people under age 18), we have secured an IRB human subjects review and exemption determination through an independent institutional review board, and was determined exempt due to not being considered human subjects research (see **Attachment 8)**. The reviewers also conducted an ethical evaluation and determined that the study does not appear to be in violation of any human subjects protections.

A.12 Estimates of Annualized Burden Hours and Costs

We estimate the total annualized response burden at 256 hours (**Exhibit A.12.1)**. The burdens for each data collection are described below. We will enroll a total of 30 youth participants ages 13 to 17 to provide message feedback. For this project, we will recruit 54 participants to account for potential drop-offs and to improve meeting the identified targets by racial and ethnic groups.

Exhibit A.12.1. Estimated Annualized Burden Hours

BURDEN HOURS

Category of Respondent	Form Name	No. of Respondents	Participation Time (minutes)	Minutes	Burden in Hours
Individual	Attachment 1 - Screener	500	15/60	7500	125
Individual	Attachment 2 - Parent Guardian Consent Form	54	20/60	1080	18
Individual	Attachment 3 - Youth Participant Assent Form	54	20/60	1080	18
Individual	Attachment 4 - Activity Guide	30	190/60	5700	95
Totals					256

According to the U.S. Department of Labor (DOL) December 2023 (the most up-to-date non-provisional data) National Occupational Employment and Wage Estimates, the average hourly wage is $ 34.27.[16] Because of the scope of this generic clearance and the variety of the types of participants, this average salary was utilized rather than attempting to estimate salaries for groups of audiences. The total annualized burden cost is estimated at **$8,773** per year.

Exhibit A.12.2 Estimated Annualized Burden Costs

Activity	No. of Respondents	Average Burden per Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Attachment 1 - Screener	500	15/60	125	$34.27	$4,283.75
Attachment 2 - Parent Guardian Consent Form	54	20/60	18	$34.27	$616.86
Attachment 3 - Youth Participant Assent Form	54	20/60	18	$34.27	$616.86
Attachment 4 - Activity Guide	30	190/60	95	$34.27	$3,255.65
TOTAL			**256**		**$8,773**

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

CDC does not anticipate providing start-up or other related costs to private entities.

A.14 Annualized Cost to the Federal Government

The contractor's costs are based on estimates provided by the contractor, who will carry out the data collection activities. With the expected period of performance, the annual cost to the federal government is estimated to be $224,025 (**Exhibit A.14.1**). This is the cost estimated includes the estimated cost of coordination with CDC, data collection, analysis, and reporting.

Exhibit A.14.1. Estimated Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct cost to the federal government		
CDC oversight of contractor and project	CDC Project Officer (25%)	$29,000
	CDC Co-Principal Investigator (5%)	$7,533
Subtotal, Direct Costs to the Government		$ 36,533
Contractor and Other Expenses		
Implementation	Data collection using online platform	$135,000
Labor hours and other direct costs	Analysis and reporting	$ 52,492
Subtotal, contracted services		$ 187,492
Total cost to the government		$224,025

A.15 Explanation for Program Changes or Adjustments

No change in burden is requested, as this is a new information collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

We will report all results in aggregate about participants using descriptive statistics, including data about race and ethnicity, age, geographic location, sex and gender, and household income. The project team will use conduct qualitative analysis to identify themes and subthemes among responses from participant feedback on the online platform. A final report and slide deck will include a summary of the methods and findings. All findings will be used internally by the CDC to make recommendations to improve communications products and strategies.

Exhibit 16.1 lists the key events and reports**.**

Exhibit A.16.1. Project Time Schedule

Activity	Time Schedule

Initiate Recruitment	June 15, 2024
Initiate Data Collect Data	July 1, 2024
Analyze Data and Report	August 1-August 30, 2024

A.17 Reason(s) Display of OMB Expiration Date Is Inappropriate

OMB Expiration Date will be displayed on necessary materials and documents.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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