

**GenIC Clearance for CDC/ATSDR
Formative Research and Tool Development**

**Formative Research for Spanish-Language
Drug Overdose Messages**

Supporting Statement A

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12. IRB Determination Letter

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

NCIPC DOP has a need for tailored communications around illicit drug use, prescription opioid misuse, and drug overdose for Hispanic/Latinx Spanish-speaking, and bilingual individuals. In 2021, to support drug overdose prevention, DOP launched four [campaigns](#) focused on polysubstance use, fentanyl, naloxone, and stigma/recovery. Messages and concepts were developed primarily with and for English-speaking audiences.

Drug overdose deaths are increasing in Hispanic populations, yet little is known about how the drug overdose epidemic is impacting Hispanic/Latinx communities. Overall, overdose mortality rates have increased steadily since 2015, with Hispanic/Latinx individuals experiencing a large increase in drug overdose rates from 2019-2020 (40.1%), from 9.5 deaths per 100,000 people to 13.7 deaths per 100,000 people.^{1,2}

Multiple determinants contribute to increased risk for drug overdose and create barriers to recovery for Hispanic/Latinx individuals. Social and cultural factors include stigma in the Hispanic community linked to mental illness; and physicians' negative attitudes toward individuals with substance use disorder, may prevent Hispanics from seeking care for drug use disorders.³ These stigmas are likely exacerbated by the cultural, linguistic, access, and communication challenges Hispanic/Latinx populations experience in healthcare.

Even as overdose deaths increase in racial and ethnic minority groups, most opioid and substance use research has focused on white populations. Existing research on Hispanic/Latinx populations and drug use has identified gaps in opioid knowledge.⁴ Additionally, recent patterns in drug overdose deaths suggest disparities in the Hispanic/Latinx communities associated with gender, generation, and country or region of ethnicity.⁵ Given the social, cultural, and linguistic nuances of Hispanic/Latinx audiences, message and concept testing of Spanish-language messages is critical to ensure drug overdose prevention messages are clear, culturally appropriate, and impactful.

A.1.2 Privacy Impact Assessment

Contractors and anyone listening to the project will be required to sign a privacy agreement prior to the start of the project (**Attachment 5.1**). CDC's contractor, Brunet-García, will retain survey responses on secure servers or in locked file cabinets; only project staff members will be able to access the servers via password-protected computers. Survey findings will be reported in aggregate form and all data collected separately from participants' names and identifying information. All survey 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.

A.1.3 Overview of the Data Collection System

CDC's contractor, Brunet-García, will use a mixed-methods approach to collect quantitative and qualitative data from Spanish-speaking monolingual and bilingual individuals ages 18-64. We will use a

survey to collect quantitative data and interviews and focus groups to collect qualitative data. Below we describe each data collection system.

Quantitative Data System: We will develop two (2) 50-item 15-minute surveys to test messages from four (4) drug overdose prevention campaigns. We will collect this data from a non-probability sample of individuals aged 18-34 that reflect national demographic characteristics and drug use data of the Hispanic population: 50% male and female and 20% who have previously used drugs (22% of Hispanics report having used an opioid in the last year)^{6,7} We expect approximately 30% of the samples, to indicate they have a friend or family member who uses drugs.⁸ There are no set targets for individuals who have administered naloxone, given there is no data around magnitude of naloxone administration from bystanders.

We will implement separate surveys due to the 50-item limit of the data collection platform (SurveyMonkey). Each survey will collect data about two campaigns as identified below:

- Survey 1: Fentanyl and Naloxone Campaigns, 500 respondents
- Survey 2: Stigma and Polysubstance Use Campaigns, 500 respondents

Qualitative Data Systems will be developed and implemented as follows:

- Interviews: We will implement 10 (interviews) from a non-probability sample of Hispanic individuals who use drugs ages 18-34, 50% male 50% female, 50% Spanish-language dominant and 50% bilingual. We develop one (1) interview guide.
- Focus Groups: We will implement four (4) focus groups of 8 (N=32 participants) from a non-probability sample of Hispanic participants who have, ages 18-55, 50% male 50% female, 50% Spanish-language dominant and 50% bilingual. We will aim to recruit about 20% of individuals who reported they have family or friends who have drugs but will not be a requirement for participation. We will develop two (2) focus group guides (each guide will collect data on two campaigns) to reduce the burden on each group and get feedback from both those whose language is primarily Spanish and bilingual individuals.

Focus Group Segment (Number of Groups)	Spanish-Primary (2 Groups)	Bilingual (2 Groups)
Focus Group Guide 1: Fentanyl and Naloxone	8	8
Focus Group Guide 2: Stigma and Polysubstance Use	8	8
Total Participants	16	16

The total respondents for this project will be a maximum of 1,042 individuals recruited by Brunet-García through vendors. The project will work with volunteer respondents.

A.1.4 Information to Be Collected

Data to be collected will include socio demographic data; knowledge, attitudes, beliefs, behaviors, and perceptions, related to drug use, misuse, and drug overdose; and reactions and receptivity to existing drug overdose prevention campaign messages and materials (**Attachment 10**). Sociodemographic data will include educational level, income, gender, race, and geographical location (zip code). Message testing items will be created in Spanish and collect information about messages related to the concepts of likeability, memorability, understanding, visual appeal, and clarity.

A.1.5 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 project is to:

1. Collect data about knowledge, attitudes, and beliefs of Hispanic/Latinx populations around drug use, misuse, and overdose.
2. Identify informational needs for materials, resources, and messaging, as well as optimal channels, trusted messengers, and touchpoints for receiving information.
3. Test messages and concepts from DOP's four drug overdose prevention campaigns.

The data collected will be used to:

1. Refine messages for the four campaigns for Hispanic/Latinx audiences.
2. Support the development of culturally and linguistically tailored products for Hispanic/Latinx audiences.
3. Ensure Spanish products meet the needs of Hispanic Spanish-speaking monolingual and bilingual audiences and inform the development of tailored Spanish products.

A.3 Use of Improved Information Technology and Burden Reduction

To reduce burden, technology will be used to collect data using surveys through online survey panels and Zoom to convene virtual focus groups and interviews. 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 types included in this request. CDC is the leading federal agency for drug overdose prevention communication work. Health messages developed by CDC are unique in their mix of the intended audience, health behavior, concept, and execution. Therefore, in most cases, there is no similar data available. We have scanned search engines, reviewed existing materials for this group, and reviewed existing published data to identify information that could facilitate message development prior to conducting any data collection.

CDC is managing other research projects and evaluations around drug use, misuse, and overdose prevention and message testing, and none of them are testing messages with Hispanic audiences and none of them are in Spanish language.

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.

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

For subcollection requests under an approved generic ICR (July 22, 2022, Vol. 87, No.140, pp. 43860), Federal Register notices are not required, and none were published.

Exhibit A.8.1. Outside Consultation

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To ensure there is no duplication or redundancy of effort across projects and programs, program staff will consult with a variety of sources on the availability of data, frequency of collection, clarity of instructions, and record-keeping, disclosure, and reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

A.9 Explanation of Any Payment or Gift to Respondents

For the online survey, no tokens of appreciation will be provided directly through this project. The surveys will be conducted through survey panels by a vendor, SurveyMonkey. As part of Survey Monkey's panel program, they provide respondents with tokens of appreciation in two ways, offering a charity donation or credits toward an Amazon gift card.

For the qualitative data collection, the project team will conduct 10 60-minute interviews with individuals who use drugs and four (4) 90-minute focus groups. Participants of focus groups will receive a \$100 token of appreciation and interviewees will receive a \$100 token of appreciation. Multiple studies using a variety of data collection methodologies have shown that offering incentives increases participation rates.⁹⁻¹²

The contractor would like to acknowledge that in our experience a higher amount of incentive might be required to reach full recruitment. Given the sensitivity of the topic and the social factors surrounding drug education for the Hispanic community, there is a risk of lower recruitment with lower incentives.

A.10 Assurance of Privacy Provided to Respondents

This submission has been reviewed by the NCIPC's Information Systems Security Officer, who has determined that the Privacy Act does not apply. The privacy assessment is provided (Attachment 5).

Brunet-García will identify, screen, and recruit potential participants through vendor Survey Monkey. Any staff will be required to sign a privacy agreement prior to the start of the project (see **Attachment 5.1** for a copy of the privacy agreement).

On the survey participants receive information regarding privacy and confidentiality on the opening page of the survey along with a valid OMB number, and contact information in case participants have questions about their rights as a participant. Participants give consent prior to the survey through the SurveyMonkey panel.

Brunet-García will retain aggregate survey data and any other project-related documents on secure servers. Only project staff members will have access to the servers via password-protected computers. Findings will be reported in summary form and no participants' names or identifying information will be collected. The vendor will provide CDC with only aggregated non-PII data. The data will be destroyed after the project has concluded.

For focus groups, participants will be asked to give verbal consent on a recording prior to the start of the focus group. Participants will receive a copy of the consent form counter signed by a Brunet-García staff member supporting the project. During the focus group, the moderator will go over key parts of the informed consent during the introduction to the focus group. The moderator will inform participants that the focus group is voluntary, and that they may choose not to answer any questions and end participation at any time. The moderator also will inform participants that Brunet-García will report findings in summary form so that participants cannot be identified and that their identifiable information will be kept secure and separate from the focus group notes and audio recordings. The moderator will inform the participant that a note-taker is listening/watching and that CDC staff may listen to the virtual focus group. The informed consent includes both the number for Brunet-García in case participants have questions about their rights as a participant, as well as the principal investigator in case participants have questions about the project itself.

CDC NCIPC's OMB and human subject's liaison has determined that IRB approval is not needed for this non-research activity (Att.12).

A.11 Justification for Sensitive Questions

There is minimal risk that questions related to drug use, misuse, 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. Questions related to gender identity may also be considered sensitive in nature. It is necessary to know the gender identity of the respondents as drug use and overdose differ by gender identity in some cases. When analyzing the data, the contractors from BG will assess differences among the different gender identities. The respondent consent form includes a statement about this risk and informs participants that they may choose not to answer a particular question if they wish and/or end the session at any time without penalty (see **Attachment 6**).

From our past experiences conducting formative research with people who use drugs, we do not expect participants to experience psychological or physical harm. In the case when participants do feel emotional discomfort and during focus groups or interviews, we will provide participants with access to a 1-hour session with a bilingual substance use counseling professional (see Attachments 2). Participants will be offered a 1-hour virtual service at the end of data collection (focus group or interview) and can opt-in to receive this benefit after the data is collected. The participant may also opt-out of data collection at any time, without penalty, and still receive the session, free of charge. After data collection, participants will receive an email thanking them for their participation and providing them with the code “GRACIAS2023” to use to indicate to the recruiter that they desire the 1-hour free counseling session. Participants can reply to that email with the code and the recruiter will respond with a phone number participants can call to reach the counselors (see Attachments 8 and 9). During the introduction we will advise participants to use the 988, suicide and crisis hotline if they feel emotional discomfort may lead to physical harm.

A.12 Estimates of Annualized Burden Hours and Costs

We estimate the total annualized response burden at 447 hours (**Exhibit A.12.1**). The burdens for each data collection are described below.

For the survey, each individual will first respond to a 1-minute survey invitation, and if they accept, they will begin the 15-minute online survey. Timing is based on our previous experience conducting research using SurveyMonkey for message testing to determine the overall burden per respondent.

For the focus groups and interviews, every individual who responds will first complete items 1-11 on the Eligibility Screener online (5 minutes). Upon qualification, a recruiter will call the participant to validate the screening information and gather additional information (items 12-T6), including demographic information (6 minutes). Those who screen in as individuals who use drugs and agree to participate in the project will participate in a 60-minute individual interview. The remainder who screen-in and agree to participate will participate in a 90-minute focus group. Consent activities will be included during the focus groups and interviews. Timing is based on our previous experience conducting research with this population using these methods to determine the overall burden per respondent.

Exhibit A.12.1. Estimated Annualized Burden Hours

BURDEN HOURS

Category of Respondent	Form Name	No. of Respondents	Participation Time (minutes)	Burden in Hours
Individual	Spanish-Language Drug Overdose Messaging Online Materials			
	Recruitment Materials (Att 8)	1,250	1/60	21
	Online Survey (Att 4)	1,000	15/60	250
	Eligibility Screener_Qual (Completed Online, items 1-11) Att 1	250	5/60	21
	Eligibility Screener_Qual (Completed by Phone, items 12-T6) Att 1.1	100	6/60	10
	Focus Group Moderator Guide (Att 2)	32	90/60	48
	Interview Guide (Att 3)	10	60/60	10
	Respondent Consent and Confirmation (Att 6)	1,042	3/60	52
	Follow up Emails (Att 7)	1,042	2/60	35
	Totals	4,726		447

According to the U.S. Department of Labor (DOL) March 2022 (the most up-to-date non-provisional data) National Occupational Employment and Wage Estimates, the average hourly wage is \$31.75.¹³ 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 \$14,176.38 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
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					Costs
Invitation to Survey	1,250	1/60	21	\$31.75	\$661.46
Online Survey	1,000	15/60	250	\$31.75	\$7,937.50
Eligibility Screening (Online)	250	5/60	21	\$31.75	\$661.46
Eligibility Screening (Phone)	100	6/60	10	\$31.75	\$317.50
Focus Group Discussion Guide	32	90/60	48	\$31.75	\$1,524.00
Interview Guide	10	60/60	10	\$31.75	\$317.50
Consent and Confirmation	1,042	3/60	52	\$31.75	\$1,654.18
Follow up Emails	1,042	2/60	35	\$31.75	\$1,102.78
TOTAL	4,726		447		\$14,176.38

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 total annual cost to the federal government is estimated to be \$163,310.77 (**Exhibit A.14.1**). This is the cost estimated by the contractor, Brunet-García, and 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)
<i>Direct cost to the federal government</i>		
CDC oversight of contractor and project	CDC Project Officer (25%)	\$29,875.25
	CDC Co-Principal Investigator (5%)	\$5,735.85
<i>Subtotal, Direct Costs to the Government</i>		
Contractor and Other Expenses		
Recruitment, data collection, analysis and reporting (contractor)	Labor hours and other direct costs	\$127,699.67
<i>Subtotal, contracted services</i>		
Total cost to the government		\$ 163,310.77

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

For online surveys, an online platform will collect and provide unidentified individual information. Brunet-García will report all results in aggregate around participants using descriptive statistics, including data about demographic characteristics, language preference, country of origin, age, generation, geographic location, income, and education level. The project team will use SurveyMonkey data analysis tools to visualize and explore trends among the data. To compare findings across groups or among demographic factors the team will analyze the data using crosstabs for selected variables of interest. Brunet-García will include aggregate data in charts and tables in the final report and slide deck. All findings will be used internally to CDC to make recommendations to improve communications products and strategies.

For focus groups and interviews, during data collection, the Brunet-García note taker will enter data into an electronic data matrix, which will be stored on a password-protected computer. Analysis of the focus group data will start immediately after completion of data collection and will be conducted under the supervision of a senior staff member with extensive experience in qualitative research. Brunet-García will conduct thematic or ground theory analysis of the data to understand participants' reactions to the messages in as rigorous and detailed manner as possible. Brunet-García will use NVIVO to support qualitative analysis. Brunet-García and CDC will review the preliminary data within one week after data collection is completed via a debriefing conference call. Brunet-García will further analyze the data in the matrices and summarize results in one summary report and one final report. Brunet-García will key data from the digital screening survey into spreadsheets and report it in descriptive data tables with accompanying narrative in the summary and final reports. All findings will be used internally to 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
Launch Online survey	October 5, 2022
Initiate participants for qualitative data	October 15, 2022
Preliminary report due	
Survey Report	October 30, 2022
Qualitative Data Reports	November 28, 2022
Final report due	December 15, 2022

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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