Request for genIC Approval
CDC/ATSDR Formative Research and Tool Development

0920-1154

CIO: National Center of Birth Defects and Developmental Disabilities

PROJECT TITLE: Reframing How We Talk About Alcohol: Public Perceptions of Excessive Alcohol Use and Related Harms

PURPOSE AND USE OF COLLECTION:

Excessive alcohol consumption leads to a variety of negative health and social consequences. Those who drink heavily have an increased risk for certain chronic diseases, such as hypertension, psychological disorders, and various forms of cancer. Excessive alcohol use also can result in societal harms, such as unintentional injuries, violence, and high economic costs (Centers for Disease Control and Prevention [CDC], 2016). Fortunately effective prevention strategies are available to reduce excessive alcohol use and its related harms. However, it is difficult to craft public health messages and communication strategies to change alcohol-related attitudes and behaviors because the public's knowledge and beliefs about excessive alcohol use and its risks are not well understood. Also, despite the fact that public health experts recommend that alcohol screening and brief counseling be provided to adults in primary care settings, data indicate that only one of six U.S. adults reported ever discussing alcohol use with a health professional. To develop an effective, consistent messaging strategy, a deeper understanding of how the public thinks and talks about alcohol is warranted.

The purpose of this study is to conduct formative research to assess perceptions and frames regarding alcohol use and its related harms, gain insights on the language the public uses when talking about excessive alcohol use, examine patient–provider communication about alcohol use, and evaluate the influence of other sources of information on the public's understanding of excessive alcohol use. The research conducted under this generic IC will be used to inform the development of consumer and provider materials and messages about excessive alcohol use and related harms.

The contractor will conduct all data collection related to the proposed study. Data collection will consist of a screening process to facilitate recruitment of participants into the study and a series of interviews and triads (small group discussions with three participants) in two phases of data collection with adults aged 21 to 55 years who drink alcohol. While both phases of proposed data collection share an overall goal of assessing perceptions and frames regarding excessive alcohol use, conducting the data collection in two phases allows the contractor to develop and test potential messages/graphical images based on the results of the first round of interviews. In Phase 1, the emphasis is on eliciting descriptions and understanding of drinking behaviors and their associated health risks from participants. This information will help determine how participants define different levels of drinking and perceive the risks related to alcohol use, which in turn will provide context for the information collected in Phase 2. With insights from Phase 1, the contractor will develop or adapt existing messages/graphical images on drinking guidelines, health effects of drinking, and drinking levels for testing with participants in Phase 2. For example, if in Phase 1, it is found that a particular health risk resonates with participants, that element may be incorporated into an updated message/graphical image. Phase 2 also explores people's response and preferences for language used in describing risks of excessive alcohol use, examines what sources people access for alcohol-related information, and investigates participant insights on patient-provider

communication around alcohol use.

The collection of these data will identify key frames, themes, and gaps in the public's knowledge which will be used to inform development of clear, persuasive messages and a communication strategy on excessive alcohol use and its related harms.

DESCRIPTION OF RESPONDENTS:
Adults aged 21 to 55 who drink alcohol (Category 1: Individuals or Households)

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. Information gathered will not be used to substantially inform influential policy decisions.
5. The study is not intended to produce results that can be generalized beyond its scope.

Name: *Mary Kate Weber*

To assist review, please answer the following questions:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [X] Yes [ ] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [ ] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [X] No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [X] Yes [ ] No

Participants will be offered a token of appreciation of $60 for their time and participation. As participants often have competing demands for their time, incentives are used to encourage participation. The payment amounts for this project were determined through discussions with the contractor, recruitment firms, and CDC staff with expertise in recruiting participants and conducting interviews about alcohol and similar health topics with the study population. This incentive will account for travel to, and participation in, a 90 minute triad or individual in-depth interview, for which dependent or child care arrangements may need to be secured, or expenses for travel may be incurred such as parking or public transportation. These challenges can present a significant burden to participants.

Numerous empirical studies have shown that incentives can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999). Incentives are also necessary to ensure that there is sufficient representation from certain groups that are more difficult to recruit such as low socio-economic groups and high-risk populations (Groth, 2010). Low or no incentives can also potentially result in a difficult and lengthy recruitment process. This can cause delays in initiating data collection, which can

lead to overall timeline delays and increased costs to the government. Ultimately, the absence of an appropriate incentive could impede the development of clear, persuasive messages and a communication strategy on excessive alcohol use and its related harms which is the goal of this project.

BURDEN HOURS

Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours
Persons aged 21–55	Study screener	300	1	10/60	50
	In-depth interviews				
	Phase 1 (Descriptive)	9	1	90/60	14
	Phase 2 (Prescriptive)	9	1	90/60	14
	Triads				
	Phase 1 (Descriptive)	18	1	90/60	27
	Phase 2 (Prescriptive)	18	1	90/60	27
	Total	**354**			**132**

FEDERAL COST: The estimated annual cost to the Federal government is $250,450. The federal government personnel estimate is based on cost of the three CDC staff and two consultants. Federal staff and consultant responsibilities include overall management and oversight of the project and provision of content matter expertise in the development of the research strategy and data collection instruments. Contractor costs include direct labor for development of instruments, data collection, analysis and reporting for both phases of the formative research. Other direct contractor costs include subcontractors, travel, and facility rental, participant recruitment and incentives; and indirect costs such as fringe, overhead, general and administrative fees.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe? [X] Yes [ ] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

The study sample will be a nonprobability-based purposeful sample. Therefore, the results are not generalizable to the general population. Statistical power is not applicable because this is a qualitative study. The audience for this research will be adults aged 21 to 55 who drink alcohol. The contractor anticipates screening 300 individuals to obtain 54 consumer participants. Data collection will consist of 18 individual interviews and 12 triads (36 participants). All in-depth interviews and triads will be conducted only one time. Participants will be recruited from Raleigh, North Carolina; Saint Louis, Missouri; and San

Diego, California. Participants will be recruited through local professional recruitment firms hired by the contractor. Most participants will come from an existing database (or list) of potential participants owned and maintained by each recruitment firm. In some cases, a recruiter may supplement their database with additional outreach (e.g., newspaper or internet ads). Screening data will be collected through a two-step process using a standardized screening instrument (**Attachment A**) to facilitate recruitment of participants into the study. The first part of the screener that includes questions about alcohol use will be done by email (potential participants will receive a link to an online version of the screener). The recruiter will then contact eligible participants by phone to administer the rest of the screener which consists of mostly demographic questions such as age, race/ethnicity, gender, and education level. The recruiters will then collect and/or confirm the names, emails and physical addresses, and phone numbers of the eligible individuals who agree to participate and have been given an appointment for an interview or triad. This information will be used to send participants a confirmation of their appointment and directions to the facility (sent by either email or regular mail). The recruiters will also place reminder calls to participants one day before their appointment.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)

    [X] Web-based or other forms of Social Media

    [X] Telephone

    [X] In-person

    [ ] Mail

    [ ] Other, Explain

2. Will interviewers or facilitators be used? [X] Yes [ ] No

    The contractor will collect information for this study in the following ways:

Screening: Screening data will be collected through a two-step process using a standardized screening instrument (**Attachment A**). The first part of the screener that includes questions about alcohol use (CDC, 2014) will be done by email (potential participants will receive a link to an online version of the screener). The recruiter will then contact eligible participants by phone to administer the rest of the screener which consists of mostly demographic questions such as age, race/ethnicity, gender, and education level.

The recruiters will collect and/or confirm the names, emails and physical addresses, and phone numbers of the eligible individuals who agree to participate and have been given an appointment for an interview or triad. This information will be used to send participants a confirmation of their appointment and directions to the facility (sent by either email or regular mail). The recruiters will also place reminder calls to participants one day before their appointment. All personally identifiable information (PII) will be maintained by the recruiters in locked file cabinets or on secure online servers. No PII will be sent to RTI or CDC.

Interviews and Triads: There will be 18 respondents for individual in-depth interviews and 36 individuals participating in triads. Data collection for this project will include participants from Raleigh, North Carolina (Phases 1 and 2); St. Louis, Missouri (Phase 1); and San Diego, California (Phase 2). All data collection

will take place through either 90-minute individual in-depth interviews (18 individuals) or 90-minute triads (36 individuals) split into two phases. Questions in the Phase 1 data collection instrument (**Attachment B**) will be the same for the individual in-depth interviews and triads. Between Phase 1 and Phase 2 data collection, the contractor will develop potential messages/graphical images informed by Phase 1 findings to be tested with participants during Phase 2 interviews. Sample messages/graphical images are located in **Attachment C**. Questions in the Phase 2 data collection instrument (**Attachment D**) will be the same for the individual interviews and triads.

Before data collection begins, participants will be given time to read the appropriate informed consent form (**Attachment E** – in-depth interview) or (**Attachment F** – triad) and ask questions. They will be given two copies of the informed consent: one to keep and one to sign to indicate consent and return to the research team. During the introduction to the individual in-depth interview or triad sessions, the moderator will review key parts of the informed consent, which will include informing participants of the following:

1. The interview is voluntary; participants may choose not to answer any question and can end participation at any time.

2. The contractor 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 interview notes and audio recordings.

3. There may be a note-taker behind a one-way mirror and CDC staff may be watching in person or via a live video stream.

The informed consent includes the phone numbers for both the contractor's IRB office in case participants have questions about their rights as a study participant, and the project director, should participants have questions about the study itself. The individual in-depth interviews and triads will be audio-recorded for the purpose of completing the final reports. All audio recordings will be destroyed after notes have been verified and no links will remain to any data collected. This project has received IRB approval through RTI International's IRB. IRB approval was granted on 09/30/2016 and will expire on 09/30/2017. The current IRB approval letter is included as **Attachment G**.

Please make sure all instruments, instructions, and scripts are submitted with the request.

- **Attachment A:** Screening Instrument
- **Attachment B:** Phase 1 (Descriptive) In-depth Interview and Triad Guide
- **Attachment C:** Phase 2 Sample Messages/Graphical Images
- **Attachment D:** Phase 2 (Prescriptive) In-depth Interview and Triad Guide
- **Attachment E:** In-depth Interview Consent Form
- **Attachment F:** Triad Discussion Consent Form\
- **Attachment G:** IRB Approval Letter

References:

Abreu, D. A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. *Proceedings of the Survey Research Methods Section of the American Statistical Association*.

Bureau of Labor Statistics. (2015). *National Compensation Survey*. U.S. Department of Labor. Retrieved July 30, 2016, from http://www.bls.gov/ncs/

Centers for Disease Control and Prevention. *Planning and Implementing Screening and Brief Intervention for Risky Alcohol Use: A Step-by-Step Guide for Primary Care Practices*. Atlanta, Georgia: Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities, 2014.

Centers for Disease Control and Prevention (CDC). (2016). Fact Sheets – Alcohol Use and Your Health. Retrieved June 18, 2016 from https://www.cdc.gov/alcohol/fact-sheets/alcohol-use.htm

Groth, SW. (2010). Honorarium or coercion: use of incentives for participants in clinical research. Journal of the New York State Nurses Association.

Shettle, C., & Mooney, G. (1999). Monetary incentives in U.S. government surveys. *Journal of Official Statistics, 15*, 231–250.

Please make sure all instruments, instructions, and scripts are submitted with the request.

Instructions for completing genIC Request for Approval for CDC/ATSDR Formative Research and Tool Development

TITLE OF INFORMATION COLLECTION: Reframing How We Talk About Alcohol: Public Perceptions of Excessive Alcohol Use and Related Harms

PURPOSE and USE: Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.

DESCRIPTION OF RESPONDENTS: Briefly describe the targeted group/groups for this collection.

CERTIFICATION: Please read the certification carefully. If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved.

Personally Identifiable Information: Provide answers to the questions.

The data collection does involve collection of sensitive or identifiable personal information (PII). All PII will be kept secure in a locked file cabinet or secure online servers.

Gifts or Payments: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

BURDEN HOURS:

Category of Respondents: Identify who you expect the respondents to be in terms of the following categories: (1) Individuals or Households; (2) Private Sector; (3) State, local, or tribal governments; or (4) Federal Government. Only one type of respondent can be selected.

Form: Provide the title of the information collection form.

No. of Respondents: Provide an estimate of the Number of respondents.

Participation Time: Provide an estimate of the amount of time required for a respondent to participate (e.g. fill out a survey or participate in a focus group).

Burden in Minutes: Multiply the Number of responses and the participation time and divide by 60.

FEDERAL COST: Estimate the annual cost to the Federal government for this collection.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents. Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

Administration of the Instrument: Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used.