GenIC Clearance for CDC/ATSDR
Formative Research and Tool Development

Supporting Statement A

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

OMB number 0920-1154

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LIST OF ATTACHMENTS

- **Goals of the study:** To assess the public's 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.

- **Intended use of the resulting data:** To inform the development of patient and provider messages and materials about excessive alcohol use and related harms.

- **Methods to be used to collect data:** In-depth interviews and triad discussions.

- **The subpopulation to be studied:** Adult consumers aged 21 to 55.

- **How data will be analyzed:** Descriptive analyses and thematic or grounded theory analysis of qualitative data.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests a 1-year Office of Management and Budget (OMB) approval for a new genIC entitled "Reframing How We Talk About Alcohol: Public Perceptions of Excessive Alcohol Use and Related Harms." The goals of this study are to assess the public's 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.

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 range of knowledge and beliefs about excessive alcohol use and its risks is not well understood. 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 required. The research conducted under this ICR will be used to inform the development of patient and provider materials and messages about excessive alcohol use and related harms.

2. Purpose and Use of Information Collection

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 results will be used to inform materials and messaging for patients and providers 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 rounds of data collection with consumers in the U.S. aged 21 to 55 years. While both rounds 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 messaging content based on the results of the first round of interviews. In the first phase, the emphasis is on eliciting descriptions and understanding of drinking behaviors and the associated types of risks. Phase Two explores people's response and preferences for language used in describing risks of excessive alcohol use, and builds on insights from the Phase One interviews by testing potential messaging content developed after the first phase.

Through the interviews and triads, the following issues will be examined: the public's perceptions and frames of excessive alcohol use and its related harms, language used when talking about excessive alcohol, patient–provider communication about alcohol use, and the influence of other sources of information on the public's understanding of excessive alcohol use.

3. Use of Improved Information Technology and Burden Reduction

This study will consist of data collection through the use of one-time interviews and triads conducted in person or electronically. In addition, minimal information will be collected by phone from potential participants to ensure they are eligible for the study. The responses from the participants are as important as the interviewers' observations of the participants and the overall data collection. Where possible and upon consent from the participant, the contractor will audio-record the data collection to capture all information and help prepare reports.

4. Efforts to Identify Duplication and Use of Similar Information

To identify duplication and use of similar information, the contractor conducted an extensive review of the literature by examining several large periodical journal databases. In addition to reviewing published information, the contractor also searched for "gray" literature by

exploring the Internet. Searches were performed using several Internet search engines. Duplication of this effort or the existence of similar information was not identified during this process.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

This is an ad hoc data collection (i.e., a one-time study to develop a messaging strategy that does not require periodic collection of data). There are no legal obstacles to reduce burden. The present study will provide the primary data needed to address the goals of this study. If this formative research was not conducted, information needed to inform the development of messaging and materials for patients and providers would not be gathered.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

The Federal Register notice was published for this collection on July 18, 2016, Vol. 81, No. 137, pp. 46680. No other public contacts and opportunities for public comments were received.

CDC project staff collaborated with the contractor and consultants on the study design, screening instruments, and data collection instruments. Contract staff are trained and experienced in conducting formative research on excessive alcohol use and other health topics. CDC also recognizes the importance of gaining valuable insights from experts who have content expertise and experience working with various consumer and provider audiences. Individuals consulted with and their roles are listed in **Exhibit A.8.1**. No major problems were identified that could not be resolved.

Exhibit A.8.1. CDC Project Staff and Other Consultants

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9. Explanation of Any Payment or Gift to Respondents

The in-depth interviews and triad discussions will each take approximately 90 minutes to complete. Participants will be offered a token of appreciation of $60 for their participation. Numerous empirical studies have shown that incentives can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999). The token of appreciation amounts were determined through discussions with contract staff with expertise in conducting interviews with the study population and interviews about alcohol. Removing the incentive would incur significant costs and timeline delays, which could threaten the development of a messaging strategy resulting from this testing. Also, incentives will ensure participation from hard-to-reach populations critical for this testing.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.

Screening and data collection instruments for both phases of the study are provided in **Attachments A** through **E**. Before data collection, participants will be given time to read the consent form (**Attachment D and E)** 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 interview, 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 contractor will conduct the formative research for this study in the following ways: *Screening*: The contractor anticipates screening up to 300 individuals to obtain 54 consumer respondents. Participants will be recruited through local professional recruitment firms hired by the contractor (hereafter referred to collectively as "recruiters"). 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. (**Attachment A)**.

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. 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 (Phases 1); and Seattle, Washington (Phase 2). All data collection will take place through either 90-minute individual in-depth interviews (18 individuals) (**Attachments B)** or 90-minute triads (36 individuals) (**Attachments C)** split into two phases. Questions in the Phase 1 data collection instrument (**Attachments B**) will be the same for the individual interviews and triads. Questions in the Phase 2 data collection instrument (**Attachments C**) will also be the same for all participants.

The 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 be maintained to any data collected.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

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**.

In the course of conducting this research, all respondents will be assured that the information will be used only for the purpose of this research and will be kept secure to the extent allowable by law, as detailed in the consent forms (see **Attachments D** and **E**). Respondents will be assured that their answers to the screener (see **Attachment A**) and data shared during the in-depth interviews or triad sessions will not be shared with anyone outside the research team and that their names will not be reported with responses provided. Respondents will be told that the information obtained will be combined into a summary report so that details of individual responses cannot be linked to a specific participant.

The contractor maintains restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a "need-to-know" basis only. The recruiters will provide the results of the screener questions for all responders, regardless of whether or not they qualify for the project. However, they will not retain responses to screening questions for those who are deemed ineligible for any other purpose outside the scope of this project. The recruiters will retain records for the duration of the project.

The study asks questions of a sensitive nature, including questions related to excessive alcohol use and its associated harms. This measurement of sensitive alcohol-related questions is necessary to create a messaging strategy aimed at reframing how the public thinks and communicates about excessive alcohol use. The study screener, **Attachment A**, will include questions from the Alcohol Use Disorders Identification Test (AUDIT), a validated alcohol

screening tool that gathers information on alcohol consumption patterns and alcohol-related harms. Study screening questions will also address race/ethnicity, gender, level of education, and age.

A.12. Estimates of Annualized Burden Hours and Costs

Exhibits A.12.1 and **A.12.2** provide details about how this estimate was calculated. The contractor anticipates screening 300 individuals to obtain 54 respondents. Screening for all interview types (in-depth interviews and triads) will take approximately 10 minutes per individual (50 burden hours). There will be 18 individuals selected for the 120-minute in-depth interviews (27 burden hours) and 36 individuals for the 90-minute triads (54 burden hours). **Total burden hours are 132.**

Exhibit A.12.A Annualized 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
	Totals	**354**			**132**

**Rounded to the nearest hour.*

Exhibit A.12.B. Annualized Cost to Respondents

Respondents	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Hourly Wage Rate	Total Burden Hours*	Total Respondent Costs**
Persons aged 21–55 Study screener	300	1	10/60	$23.23	50	$1,161.50

Persons aged 21–55 Phase 1 (Descriptive) In-depth Interview	9	1	2	$23.23	18	$418.14
Persons aged 21–55 Phase 1 (Descriptive) Triad	18	1	2	$23.23	27	$627.21
Persons aged 21–55 Phase 2 (Prescriptive) In-depth Interview	9	1	2	$23.23	18	$418.14
Persons aged 21–55 Phase 2 (Prescriptive) Triad	18	1	2	$23.23	27	$627.21
					Total	**$3,252.20**

**Rounded to the nearest hour.*
***Rounded to the nearest dollar.*

The United States Department of Labor, Bureau of Labor Statistics May,2015 http://www.bls.gov/oes/current/oes291069.htm.) data were used to estimate the hourly wage rate for the general public and for private providers for the purpose of this generic request. Each project will have cost specific to the category of the respondents. Because it is not known what the wage rate category will be appropriate for the specific projects (or even whether they will be employed at all), the figure of $20.00 per hour was used as an estimate of average hourly wage across the country.

Because the wage rate category for selected participants (or even whether they will be employed at all) is unknown, $23.23 per hour was selected as this is an estimate of mean hourly wage for all occupations across the country (Bureau of Labor Statistics, 2016). The estimated annual cost burden to participants for information collection will be $3,252.20.

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

There are no other costs to respondents or record keepers.

A.14. Annualized Costs to the Government

The average annualized cost to the Federal Government to collect this information 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 (**Exhibit A.14.1**)

Exhibit A.14.1. Government Costs

		Percent Time	**Total ($)**
Federal Government Personnel Costs	CDC Behavioral Scientist/Technical Monitor (GS-14)	10%	$12,522
	CDC Behavioral Scientist (GS-13)	5%	$5,004
	CDC Health Scientist (GS-15)	5%	$6,956
	Consultant 1	15 hours	$1,800
	Consultant 2	30 hours	$3,600
Total Contractor Costs	Personnel, fringe, overhead, general and administrative fees	n/a	$220,568
Total Annualized Cost to Government			$250,450

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

Data from the in-depth interviews and triads will be entered into an electronic data matrices by the contractor during the data collection process and stored on a password-protected computer. The contractor will conduct thematic or ground theory analysis of the data to understand participants' reactions to the interview and triad questions in a rigorous and detailed manner. Contractor analysts will analyze the data in the matrices and produce a written report describing the major findings from the in-depth interviews and triads. The key events and reports to be prepared are listed in **Exhibit A.16.1**.

Exhibit A.16.1. Project Activities and Time Schedule

Activity	Time Schedule
Identify and reserve professional recruitment firms	1 month after OMB approval
Begin recruitment	1 month after OMB approval
Complete Phase One formative research	3 months after OMB approval
Complete Phase Two formative research	5 months after OMB approval
Draft report due	6 months after OMB approval
Final report due	8 months after OMB approval

It is anticipated that Phase One data collection will commence within 1 month of receiving OMB approval with Phase Two occurring approximately one month later.

Research findings will be disseminated to a number of audiences. The main reporting and dissemination mechanism will be in the form of a final formative research report. The final report will be written in clear language that is understandable by a wide range of audiences (the target audience, practitioners, policy makers, and researchers). The final report will include the following information: an executive summary, overview of background literature to provide contextual information about the purpose of the research, a detailed summary of the formative research methods and results, a discussion of findings, strengths and limitations of the research, and future directions regarding message strategy.

A.17. <u>Reason(s) Display of OMB Expiration Date is Inappropriate</u>

Approval to eliminate the expiration date is not needed.

A.18. <u>Exceptions to Certification for Paperwork Reduction Act Submissions</u>

There are no exceptions to the certification.

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