**GenIC Clearance for CDC/ATSDR**

**Formative Research and Tool Development**

**Supporting Statement B**

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

**OMB number 0920-1154**

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**B. Collections of Information Employing Statistical Methods**

1. **Respondent Universe and Sampling Methods**

 The purpose of this study is to conduct individual in-depth interviews and triads in two rounds of data collection with consumer groups in the United States aged 21 to 55 years 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. The research results will be used to develop a messaging strategy aimed at reframing the way the public thinks and communicates about excessive alcohol use and will support the promotion and conduct of alcohol screening activities by clinical professionals. Qualitative methods provide flexible in-depth exploration of the participants’ perceptions and experience, and the interviews yield descriptions in the participants’ own words. Qualitative methods also allow the interviewer flexibility to pursue relevant and important issues as they arise during the discussion. Furthermore, a qualitative approach will allow the researcher to capture subtle nuances in participants’ attitudes, beliefs, and feelings related to the issue of excessive alcohol use. Discussion guides (in-depth interviews and triads) include probes to ensure that input on specific items of interest is obtained while open-ended questions ensure that participants’ responses and perceptions are fully addressed and captured (**Attachments B** and **C)**.

 The study sample will be a nonprobability-based purposeful sample as opposed to probability-based. Therefore, the results are not generalizable to the general population. The contractor anticipates screening 300 individuals to obtain 54 consumer respondents. There will be 18 respondents for the in-depth interviews and 36 individuals participating in triads. All interviews and triads will be conducted only one time. Participants will be recruited from Raleigh, North Carolina; Saint Louis, Missouri; and Seattle, Washington. Statistical power is not applicable because this is a qualitative study.

### Study Population

 The audience for this research will be adult consumers aged 21 to 55.

## **B2. Procedures for the Collection of Information**

The contractor will select and reserve professional recruitment firms (with CDC’s approval) in each city. The firms, under the oversight of the contractor, or contractor staff will recruit study participants for the in-depth interviews and triads. The contractor will use a screener (**Attachment A)** to identify eligible participants for both types of interviews.

As participants are recruited for the in-depth interviews and triads, recruitment grids will be prepared to keep track of recruitment. The recruitment grids will list participants’ first names, some demographic information obtained from the screener, and participants’ Alcohol Use Disorders Identification Test (AUDIT) scores. The grids will not contain any personal identifying information. The recruitment grids will be stored in a locked file cabinet or on a password-protected project share drive at the contractor’s worksite and at each professional recruitment firm. The professional recruitment firms will destroy their copies of the recruitment grids after data collection is completed in that city. The contractor and CDC will have copies of the recruitment grids to describe the study sample. These copies of the recruitment grids will be kept in locked file cabinets or on a password-protected project share drive at the contractor’s worksite and CDC for the duration of the study.

Recruitment will begin at least 4 weeks before the in-depth interviews or triads are scheduled. The contractor will closely communicate with each professional recruitment firm to monitor the recruitment and troubleshoot any problems that may arise. The contractor will keep CDC apprised of recruitment progress and will make adjustments if needed. Identification of recruitment facilities and recruitment will begin once Institutional Review Board (IRB) and Office of Management and Budget (OMB) clearances are received. Typically, recruitment begins within a month of receiving OMB clearance and recruitment takes about 1 month to complete. Dates will be assigned to each activity on the timeline for tracking and monitoring purposes after receiving IRB and OMB clearances.

Personal identifying information from potential participants participating in the in-depth interviews and triads will be maintained and protected to the extent allowable by law. At each facility, recruitment staff will sign a privacy agreement acknowledging the requirement to treat all data in a secure manner and not disclose any data, unless otherwise compelled by law. At each facility and at the contractor’s worksite, the screeners will be kept in locked file cabinets or secure servers. All identifying information (name, address, telephone number) will be recorded on the last page of the screener, which will enable the facility and/or the contractor to send reminder letters/e‑mails and make reminder phone calls. The last page of the screener will be torn off and destroyed after the in-depth interviews/triads are conducted. Local professional recruitment firms will send the screeners (without the last page) to the contractor. The screeners will be stored in a locked file cabinet or on a secure server at the contractor’s worksite throughout the duration of the project. Once the project ends, the screeners will be destroyed. No identifying information about participants will be kept at the professional recruitment firms after the interviews are completed, and the professional recruitment firms will not send any identifying information to the contractor or CDC.

Reminder letters/e-mails for the in-depth interviews and triads will be sent to potential participants prior to the data collection, giving them directions to the study site.Confirmation calls or e-mails will also be made 1 to 2 days prior to the in-depth interview/triad to ensure that all recruits are confirmed.

Once the potential participant comes to the study site and checks in for the in-depth interview or triad, he/she will be given a consent form (see **Attachments D** or **E**). The individual will be given time to read the consent form on his/her own, and a trained contractor will be available to answer any questions. If the participant agrees to be in the study, he/she will provide consent. The participant will be given a copy of the consent form to keep for his/her records, and then data collection will proceed. Questions in the Phase 1 data collection instrument (**Attachments B**) will be the same for both in-depth interviews and triads. Questions in the Phase 2 data collection instrument (**Attachments C**) will also be identical for each group type.

All participants, regardless of interview method used, will be reminded that they can refuse to answer any question and they can stop their participation in the study at any time without penalty. Contractor staff will mail or personally take all forms back to the contractor’s worksite after the interviews are completed in a particular city. The consent forms will be stored in a locked file cabinet at the contractor’s worksite for the duration of the project. Once the project ends, all forms will be destroyed.

On a one-time basis, 18 individuals will participate in a 90-minute in-depth interview and 36 individuals will participate in a 90-minute triad. The in-depth interviews and triads will be conducted in person by a professionally trained moderator. Data collection will occur at professional focus group facilities in three locations (Raleigh, North Carolina; Saint Louis, Missouri; and Seattle, Washington).

Each data collection for the in-depth interviews and triads will last a total of 90 minutes. In addition to the moderator, an additional contractor will attend the sessions to take notes on a laptop computer and to coordinate logistics of checking in participants and obtaining informed consent. CDC staff member(s) may also attend to observe the in-depth interviews and triads in person or via video streaming. 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.

## **B3. Methods to Maximize Response Rates and Deal with No Response**

The following procedures will be used for the in-depth interviews and triads to maximize cooperation and achieve the desired participation rates:

* Professional recruitment staff will recruit participants**.**
* Reminder letters/e-mails will be sent to participants with directions to the research site and reminder phone calls placed 1 to 2 days prior to the scheduled data collection. Participants will not be contacted again after the in-depth interview/triad is over.
* A token of appreciation will be provided to thank participants for their time and participation in the study (please see **Section A.9** for more information about the token of appreciation).

## **B4. Test of Procedures or Methods to Be Undertaken**

To estimate the burden for administering the screening questionnaire, the contractor consulted two different project team members. The project team members conducted mock screening interviews and provided affirmative responses to most or all questions that led to further follow-up questions. In this way, the burden estimate most closely resembles a maximum average burden, because almost all screening questions were presented in the interview. In addition, the project team members deliberately read each item at a slow rate of speed. The project team members estimated the maximum average burden for the screening instrument to be 10 minutes. The screening instrument is shown in **Attachment A**. The interview instruments were not pilot tested with members of the public, but extensively reviewed by researchers experienced in conducting qualitative data collection tasks.

## **B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

The individuals consulted on technical and statistical issues related to data collection are listed below. The data will be collected and analyzed by the study contactor, RTI International.

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