Developing Effective Messages about Excessive Alcohol Consumption: Formative Focus Groups with Adult Drinkers and Abstainers

November 28, 2016

Supporting Statement Part A

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D. Informed Consent Form
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F. Activity Worksheet: Profile of an Excessive Drinker
G. Activity Worksheet: Excessive Drinking Problems
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I. Project Announcement – Chesapeake IRB Exemption Determination

Goal of the study: To understand the current knowledge, perceptions, and attitudes related to excessive alcohol consumption across various audience segments.

Intended use: Findings from this information collection will guide the CDC Alcohol Program in the development and refinement of targeted messages to effectively communicate the problem of excessive alcohol use, and encourage support for effective prevention strategies. The ultimate goal of the subsequent messaging is a reduction in binge drinking, which will in turn reduce alcohol-related injuries and deaths among adults.

Methods to be used: We plan to conduct four focus groups in each of three locations for a total of 12 groups. For each group, eight potential participants will be recruited, anticipating six to participate.

The subpopulation to be studied: All focus group participants will be aged 21-64, will be conversant in English, and will meet additional criteria related to drinking behavior in order to segment participants as Abstainers, Non-Excessive Drinking Young Adults, Non-Excessive Drinking Mid-Life and Excessive Drinkers.

How the data will be analyzed: Focus group discussions (transcripts/recordings) will be examined using qualitative content coding. Themes within and between groups will be examined along with points of consensus and disagreement/variation between groups.

Supporting Statement A

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests Office of Management and Budget (OMB) approval of a qualitative focus group project to develop effective messages about excessive alcohol consumption for the Alcohol Program within the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). OMB approval is requested for one year.

The Information Collection Request (ICR) for this project is classified as new. Information collection is authorized by the Public Health Service Act (Attachment A).

Excessive alcohol use, including binge drinking, is responsible for approximately 88,000 deaths in the U.S. annually—including one in 10 deaths among working-age adults ages 20–64 (Stahre et al., 2014). On average, for each death due to alcohol, an individual's life is cut short by 30 years (Centers for Disease Control and Prevention, 2004). Excessive alcohol use can also lead to motor vehicle crashes; intimate partner violence; and risky sexual behaviors, increasing the risk of HIV, other sexually transmitted infections, and unintended pregnancy. Over time, excessive alcohol use can lead to alcohol dependence, liver disease, high blood pressure, heart attack, stroke, and certain kinds of cancer. Furthermore, in 2010, excessive alcohol use cost the United States Government $249 billion, or $2.05 per drink (Sacks et al., 2015).

Binge drinking (defined as four or more drinks on an occasion for women or five or more drinks on an occasion for men) accounts for more than half of the deaths and three-quarters of the economic costs of excessive drinking. More than 38 million U.S. adults binge drink about four times a month, averaging eight drinks per binge (Centers for Disease Control and Prevention, 2012). However, most (90%) binge drinkers are not alcohol dependent (Esser et al., 2014), which presents an opportunity for prevention through messages that improve voluntary compliance with recommended guidelines. States and communities can prevent binge drinking by supporting evidence-based strategies, such as those recommended by the Community Preventive Services Task Force; however, these strategies are underused. Understanding the type of information and messages that the larger community—those who drink but not excessively or abstain from drinking in addition to those who engage in binge drinking—will be essential in developing the communication strategy for future outreach.

The CDC Alcohol Program aims to (a) improve public health surveillance on excessive alcohol use, particularly binge and underage drinking, and related health outcomes, (b) increase applied public health research on alcohol-related health impacts and population-based strategies to prevent excessive alcohol consumption, (c) build state public health

capacity in alcohol epidemiology, and (d) provide national public health leadership for preventing excessive drinking.

To that end, the goal of this new collection is to understand the current knowledge, perceptions, and attitudes related to excessive alcohol consumption across various audience segments. Findings from this information collection will guide the CDC Alcohol Program in the development and refinement of targeted messages to effectively communicate the problem of excessive alcohol use, and encourage support for effective prevention strategies. The ultimate goal of the subsequent messaging is a reduction in binge drinking, which will in turn reduce alcohol-related injuries and deaths among adults.

A2. Purpose and Use of Information Collections

Information obtained through this project will guide the CDC Alcohol Program in the development and refinement of targeted messages to effectively communicate the problem of excessive alcohol use, and encourage support for effective prevention strategies. Specifically, focus group participants will answer questions regarding their current knowledge, perceptions, and attitudes related to excessive alcohol consumption in order to compare results across audience segments and develop targeted messages.

CDC has contracted with Fors Marsh Group, LLC (FMG), to develop and execute this project on behalf of the CDC. The project will consist of 12 focus groups, each with approximately six adults ages 21 and older. Participants will be identified using standard recruiting procedures that employ screening questions about age, current drinking habits, gender, and race and ethnicity. Recruitment will continue until FMG obtains a diverse sample of the required number of participants for each group. Groups will be segmented by their drinking profile; this information will be gathered during the screening process. Groups will otherwise be diversified by race and ethnicity as well as gender.

FMG plans to collect the information through 12 in-person focus groups led by a professional moderator with experience leading focus groups on sensitive topics including alcohol use. The moderator will use a semi-structured discussion guide to encourage participants to share their current understanding, perceptions, and attitudes toward excessive alcohol consumption. The moderator will encourage participants to respond openly and spontaneously. All sessions will be audio-recorded and transcribed for reporting purposes. Participants will be notified of and agree to this recording during screening and informed consent processes. Discussions will take place in focus group facilities. Each focus group will last 90 minutes. The focus group may also be observed by the CDC and other CDC contractor staff.

A3. Use of Improved Information Technology and Burden Reduction

FMG will conduct information collection in person during the focus groups and screen participants via telephone. Other than two worksheets to be completed during the session (see Attachments F and G), there will be no paper documents to complete as part of the information collection.

A4. Efforts to Identify Duplication and Use of Similar Information

The information that the CDC collects is not available from any other source. The CDC Alcohol Program is the only Federal program investigating messaging related to excessive drinking in the nondependent adult population. Per knowledge and past experience from CDC Alcohol Program staff and the RFP, no past data collection efforts have been previously conducted with these audiences to tests the messages the program has been using and to further develop targeted messaging.

A5. Impact on Small Businesses or Other Small Entities

Respondents in this project will be members of the general public and not business entities. No impact on small businesses or other small entities is anticipated.

A6. Consequences of Collecting the Information Less Frequently

This effort is a one-time data collection. Individuals who meet the project inclusion criteria will participate in one 90-minute focus group. Without the information collection requested for this project, it would be difficult to develop effective messages that will strongly resonate with the intended audience. The intended audience includes different segments that have unique barriers and perceived benefits to reducing alcohol consumption; this project aims to better understand these in order to develop effective messaging. Failure to collect this information could reduce effective use of the CDC Alcohol Program's resources to prevent excessive alcohol consumption. Careful consideration has been given to the project design to effectively balance the information collection objectives with participant burden.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with Title 5 of the Code of Federal Regulations (5 CFR) section 1320.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. On July 6, 2016, CDC published a Notice in the Federal Register (Vol. 81, No. 189, pp. 44024-44025; see Attachment B-1). CDC received 2 comments from 1 individual. Attachment B-2 provides a summary of public comments.

B. The following individuals outside of the agency have been consulted on project design and material development (2015-2016):

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There are no major unresolved problems stemming from this consultation.

A9. Explanation of Any Payment or Gift to Respondents

Participants will receive an incentive of $75 as a token of appreciation for their participation in the project. The $75 incentive was identified based on (1) the level of involvement needed to participate in the 90 minute focus group, (2) the sensitive nature of the discussion topics regarding alcohol use, (3) the potential recruiting difficulties with identifying potential respondents who fit the inclusion criteria and are willing to share their personal experiences, and (4) market research in multiple potential markets regarding recommended incentive rates for this effort.

As participants often have competing demands for their time, incentives are used to encourage participation. The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate. In this particular information collection, we will be asking respondents to share personal experiences and perspectives as well as provide thought-intensive, open-ended responses that require a high level of participation. When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation (Halpern, et al., 2004).

Incentives must be high enough to equalize the burden placed on respondents with respect to their time and cost of participation (Russell et al., 2000) as well as provide enough motivation for them to participate in the project. If the incentive is not adequate, participants might agree to participate and then not show up or drop out early. Low participation could result in inadequate information collection or, in the worst cases, loss of Government funds associated with facility rental as well as moderator and observer time (Morgan & Scannell, 1998).

Additionally, this can cause a difficult and lengthy recruitment process that, in turn, can cause delays in launching the information collection, both of which lead to increased costs. Incentives are also necessary to ensure adequate representation among harder-to-recruit populations such as low socio-economic groups and high-risk populations (Groth, 2010).

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CIO’s Information Systems Security Officer reviewed this submission and determined that while the Privacy Act is not applicable, the appropriate security controls and Rules of Behavior should be incorporated to protect the confidentiality of information, proprietary, sensitive, and Personally Identifiable Information (PII) the Contractor may come in contact

with during the performance of this contract. All information will be collected with an assurance that the respondents' responses will remain private to the extent allowable by law.

The consent form (see Attachment D) will contain a statement that the respondent's identity will not be linked to his or her session responses at any time; instead, each participant will be assigned a unique identifier (UID) at the time of recruitment. This UID will not be tied to a participant's consent form. Focus group questions will not ask participants to provide identifying information as part of their responses, and responses captured by the audio recordings will be available at the group level only. Participant names and contact information will be temporarily linked to their screener responses to determine eligibility; however, only the recruiting team will have access to this linked information—which will be password-protected at all times and destroyed immediately upon completion of the sessions. All project information will remain in a secured area or on a password-protected computer. CDC will receive group-level transcripts and a summary report. To ensure participant privacy, the contractor will redact the recordings and transcripts of any personally identifiable information (PII); no identifying information will be provided to CDC at any time.

All participants will be notified that the sessions will be audio-recorded during screening and when signing the informed consent form. By verbally agreeing to participate in the sessions at the time of recruitment and signing the consent form, participants will consent to being audio-recorded.

The contractor will also produce transcriptions of the digital recordings to assist in report writing and to provide the CDC with a written record of the sessions. Electronic copies of the transcripts will be supplied. The transcript for a given group will be available to the CDC within two weeks of the completion of the information collection. The contractor will redact the transcripts for any personally identifiable information (PII).

Respondents' discussions will remain private to the extent provided by law. The moderator's guide and consent form will contain a statement that no one will be able to link a respondent's identity to his or her responses. Identifying information will not be included in the files delivered by contractors to the agency.

Neither independent contractors nor focus group agencies will share personal information regarding participants with any third party without the participant's permission unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or other legal process. Identifying information will not be included in the transcripts and digital recordings delivered to the agency. All project information received by the CDC will remain in a secured area. No project information will contain identifying information.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

Chesapeake Institutional Review Board (IRB) has reviewed and approved the project protocol and materials (see Attachment J for approval letter).

Sensitive Questions

Some studies require the inclusion of people who match selected characteristics of the target audience that the CDC is trying to reach. This requirement might require FMG to ask potential recruits questions about their drinking behavior on the initial screening questionnaire. Potential participants will be informed that this is being done to make sure that the CDC speaks with the kinds of people for whom its messages are intended. FMG will assure respondents that providing the information is voluntary and that it will be treated as private to the extent allowable by law. Respondents will also be asked various demographic questions such as race/ethnicity, age, gender, education status, and household income. FMG will use these questions to ensure diverse opinions are gathered. All information on race/ethnicity will fully comply with the standards of OMB Statistical Policy Directive No. 15, October 1997 (http://www.whitehouse.gov/omb/fedreg/1997standards.html).

CDC alcohol-related communications might be concerned with the prevention of premature mortality or morbidity from overconsumption as well as potential risks to others. This might involve asking questions about (or discussing) how one perceives his or her own personal risk for poor health outcomes or other behavioral or legal consequences of excessive alcohol use. This information is needed to gain a better understanding of the target audience so that the messages, strategies, and materials designed will be appropriate and sensitive. Questions of this nature—while not as personal as those about sexual behavior or religious beliefs, for instance—still require some sensitivity in how they are worded and approached. In face-to-face information collections, questions of this kind are generally asked later in the interview or group discussion, when respondents are more comfortable with the interview situation and are more at ease with the interviewer/moderator. Participants are informed before actual participation about the nature of the activity and the voluntary nature of their participation. The interviewer/moderator makes it clear to participants that they do not have to respond to any question that makes them uncomfortable.

Potentially sensitive information (e.g., from screening questionnaires, audiotapes, and transcripts) is not retained once the information has been extracted and aggregated. The information never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

A12. Estimates of Annualized Burden Hours and Costs

The burden estimate is based on prior experience with in-person studies similar to the plan presented in this document. The project will consist of 12 focus groups, each with approximately six adults. FMG plans to screen approximately 288 adults in order to obtain a sample size of 72. Table 1 illustrates the estimated annualized burden hours.

Table 1. Estimated Annualized Burden Hours

Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Adults aged 21–64	Questionnaire/ Screener	288	1	5/60	24
	Focus Group	72	1	1.5	108
Total					132

The estimated total cost to respondents for this information collection is estimated to be $3,332. To compute the total estimated annual cost, the total burden hours were multiplied by the average hourly earnings for each adult participant in December 2015, according to the Bureau of Labor Statistics, Current Employment Statistics Survey.

Table 2. Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Adults aged 21–64	Questionnaire/ Screener	24	$25.24	$605.76
	Focus Group	108	$25.24	$2725.92
Total				$3331.68

A13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time.

A14. Annualized Cost to the Government

Estimates of annualized cost to the government are included in the table below. These include contract costs plus the personnel costs of federal employees involved in project

oversight. Annualized salaries and wages are based on the Office of Personnel Management's 2015 Salary table for the locality pay area of Atlanta-Sandy Springs-Gainesville, GA-AL [https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/15Tables/html/ATL.aspx]

Table A.14.1 Estimated Annualized Cost to the Federal Government

Annualized Cost to the Government	Average Annualized Cost
[Grade 15 Step 5], [$137,401] at 7% time to provide project oversight.	$9,618
[Grade 14 and Step 5], [$116,808] at 12% time to provide project oversight.	$14,017
Contractor support for project leads	$8,533
Contractual costs which includes cost for personnel, planning, information collection, analysis and report writing.	$134,231
Total	$166,399

A15. Explanation for Program Changes or Adjustments

This is a new information collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

This information collection relies on qualitative methods and is not intended to yield results that are statistically projectable. Findings from this information collection will guide the CDC Alcohol Program in the development and refining of targeted messages to effectively communicate the problem of excessive alcohol use, and encourage support for effective prevention strategies.

OMB approval is requested for one year. The project timeline is outlined in Table 3.

Table 3. Project Timeline

Item	Timeline
Notification of initiation of focus group recruiting	Within 2 weeks following OMB approval
Notification of initiation of focus group fielding	Within 3 weeks following initiation of focus group recruiting

Executive Summary/Topline Findings	Four weeks following end of focus group fielding
Draft messages for each segment	Two months following end of focus group fielding
Focus Group Final Report	Three months following end of focus group fielding

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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