Focus Groups about Alcohol Consumption during Pregnancy

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A. Justification

A.1 Circumstances Making the Collection of Information Necessary

On January 9, 2009, CDC received OMB approval for the generic concept of health marketing (Health Marketing, 0920-0798) to provide feedback on the development, implementation and satisfaction regarding public health services, products, communication campaigns and information.

Under Health Marketing, OMB has agreed to expedite review of proposals for data collections for survey/informative materials development and customer satisfaction surveys only. OMB will generally review such requests within ten business days.

Background

According to the Centers for Disease Control and Prevention's (CDC's) Behavioral Risk Factor Surveillance System (BRFSS), in 2006, across the United States and territories, the median rate of alcohol use (one or more drinks in past 30 days) for women of childbearing age (between 18–44 years) was 54 percent. Even women who are planning to conceive a child in the next 12 months continue to drink alcohol, and 54 percent of these women reported alcohol use within the past month on the 2002 and 2004 BRFSS (Anderson, Ebrahaim, Floyd & Atrash, 2006). Since many women do not recognize that they are pregnant until 6 weeks or later into pregnancy (Floyd, Decoufle, & Hungerford, 1999), this high prevalence of use among preconception women poses a risk to fetal development.

Drinking alcohol during pregnancy can result in lifelong conditions known as fetal alcohol spectrum disorders (FASD), marked by abnormal facial features, growth deficiencies, and central nervous system problems along with possible problems with learning, memory, attention span, communication, vision, and/or hearing (CDC, 2008). All FASDs are 100 percent preventable, as long as women refrain from consuming alcohol while pregnant. However, alcohol-related birth defects remain among the most common preventable causes of birth defects within the United States. To address this public health concern, Congress mandated that the Secretary establish "a comprehensive Fetal Alcohol Syndrome and Fetal Alcohol Effect prevention, intervention and services delivery program" that includes "public and community awareness programs concerning Fetal Alcohol Syndrome and Fetal Alcohol Effect" through the Public Health Service Act, (42 U.S.C. Section 280f), as amended by Public Law 105-392. A copy of this legislation is included as Attachment 1.

While researchers continue to examine the effects of alcohol use during pregnancy, the U.S. Surgeon General, CDC, and other health authorities currently recommend abstaining from alcohol use throughout pregnancy, because there is no known safe amount or time to drink during pregnancy (CDC, 2008). Yet pregnant and potentially pregnant women continue to consume alcohol. These recommendations also apply to sexually active women of childbearing

age who drink alcohol and use ineffective measures of birth control, because they may become pregnant and not know for some time. Conflicting messages in the media generated by scientists, policy makers, advocates, health care providers, and women (pregnant or not) may contribute to the decisions to drink prior to conception or during pregnancy by creating a context of confusion for women. This project proposes to look at the reasons why women drink prior to and during pregnancy to inform the development of future educational and media efforts to address this serious issue.

Authorization to conduct this activity is contained in the Public Health Service Act (42 USC 241) Section 301. A copy of the legislation is included as Attachment 2.

Overview of the Data Collection System

Data collection for *Focus Groups about Alcohol Consumption during Pregnancy* will consist of 90-minute discussions, with from five to eight participants in each of the 20 focus groups (see Attachment 3 – Focus Group Guides). At the end of the discussion, focus group participants will complete an 18-question paper-and-pencil questionnaire (see Attachment 4 – Focus Group Participant Questionnaire). Questions are either multiple-choice or write-in responses.

RTI International will conduct the focus groups, and will store resulting data for only one year after the focus group completion.

Items of Information to be Collected

The types of information to be collected include information about the participant's demographics, such as age and race/ethnicity. Questions about the participant's attitudes, perceived norms, and information sources regarding alcohol use and pregnancy predominate.

Notes, discussion transcripts, and questionnaires from the focus groups will not be in an identifiable form. However, the recruitment firm (Bernett Research Services, Inc.) will collect limited information in identifiable form (IIF) through the screener (see Attachment 5 – Screening Instrument) in order to place women in the appropriate focus groups.

A.2 Purpose and Use of Information Collection

The National Center on Birth Defects and Developmental Disabilities (NCBDDD) of the Centers for Disease Control and Prevention (CDC) is requesting approval to conduct focus groups to assess women's knowledge, skills, attitudes, and behaviors regarding alcohol consumption during pregnancy. Media, social and other influences on those women's knowledge, attitudes and behaviors related to alcohol use and pregnancy will also be examined. This project proposes to look at the reasons why women drink prior to and during pregnancy in order to inform the development of future educational and media efforts to address this serious issue, which will advance the aforementioned Congressionally mandated objectives of the NCBDDD. If we do not conduct this formative project, CDC will not have the information it needs to create up-to-date and effective educational and media efforts.

We will use the focus group methodology to address the following general questions:

- What do women of childbearing age know about alcohol consumption and reproductive health outcomes?
- What social, attitudinal, skill and belief factors influence women's decisions about consuming alcohol when they are or might be pregnant?
- What sources of information (i.e., media, physicians, family, friends, etc.) have provided women with their knowledge regarding alcohol intake during pregnancy? Which of the sources most influence these women's knowledge and beliefs? In particular, what information and advice are they getting from their health care providers about pregnancy/pregnancy preparation and alcohol consumption?

We plan to segment the focus groups as shown in Exhibit 1. To be eligible to participate in the focus groups, participants must meet all of the following criteria: age 18 to 35, English speaking, drank alcohol in past 3 years (for other than religious reasons), not currently pregnant, and White, Black/African American, or Hispanic/Latina race/ethnicity. Women must also meet one of the following criteria: gave birth in the past 12 months OR trying or planning to get pregnant in the next 12 months OR sexually active, able to get pregnant, drank at least one drink of alcohol in past 90 days, AND do not demonstrate effective birth control use.

Exhibit 1. Distribution of Focus Groups by Audience Segment and Subgroup

	White Age 18–24	Black/ African American Age 18–24	Hispanic/ Latina Age 18–24	White Age 25–35	Black/ African American Age 25–35	Hispanic/ Latina Age 25–35	Total**
Women* not trying to get pregnant but who are at risk of having an alcohol-exposed pregnancy	1	1	1	1	1	1	6
Women* who are currently trying to get pregnant or who plan to become pregnant in the next year	1	1	1	1	1	1	6
Women* who have had a baby within the past year	1	1	1	1	1	1	6
Total							18**

*All participants will be nonpregnant women of childbearing age (18–35 years).

** Two additional groups (totaling 20 groups) will be conducted to ensure that we provide a representative overall sample selected from the subpopulations represented by the segments in the table. The final decision for the segmentation of the two groups will be based on CDC's preferences and the recruitment results from the first 18 groups.

Privacy Impact Assessment Information

The focus groups and short questionnaire will include questions on sensitive information such as alcohol use during pregnancy and reproductive health. However, we will take measures to ensure the participant's confidentiality and privacy (see section A-10).

Information in identifiable form (IIF) through the screener will be collected by the focus group recruiting firm, but only for recruiting purposes.

A.3 Use of Improved Information Technology and Burden Reduction

Due to the nature of this project, incorporating improved information technology for the purpose of data collection is not feasible. We will employ focus groups to gather information. By approximating a natural discussion format, focus groups provide the opportunity to observe the interaction and potential influence of group participants, which encourage further insights into attitudes, perceptions, and opinions that would otherwise be unlikely to emerge in the absence of group dynamics.

Upon consent from the participants, we will audio record the focus group discussions to capture all information and assist with the preparation of reports. The use of electronic reporting is typically not feasible for this form of qualitative work.

A.4 Efforts to Identify Duplication and Use of Similar Information

There have been no formal efforts to identify duplication because program staff, through extensive contacts with organizations and individuals in both the private and public sectors, know that there are no similar data available. RTI International, the CDC contractor for this project, conducted a comprehensive scientific literature review of multidisciplinary fields, including medicine, public health, communication, and behavioral science. In addition to reviewing published information, the literature review included "gray" literature obtained from CDC funded projects, and literature obtained through the use of Internet and other search engines (such as Google and Medline). This project builds on the information found through the literature review, but the information currently available has significant gaps, is out-dated, and does not adequately address the topics of interest. There is no other project that duplicates the proposed efforts.

A.5. If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.

There is no burden on small businesses or small entities. No small businesses will be involved in this activity. We will schedule all focus groups at the convenience of the participant and will not impact the participant's employer.

A.6 Consequences of Collecting the Information Less Frequently

This is a one-time request; therefore, it is not possible to ask participants to participate in the focus groups less frequently. There are no legal obstacles to reduce the burden.

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

This request fully complies with the regulations regarding the guidelines of 5 CFR 1320.5. There are no special circumstances contained within this application.

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

A. The 60-day Federal Register Notice (FRN) for 0920-0798 was published in the Federal Register on May 14, 2008, Vol. 73, No. 94, pp. 27833-27834. The 30-day FRN was published on July 24, 2008, Vol. 73, No. 143, pp. 43241-43242. No public comments were received.

B. The CDC team collaborated with RTI International staff (contractor) on the design, screening instruments, focus group guides, and questionnaire. RTI staff is trained and experienced in formative focus groups.

A. 9. Explanation of Any Payment or Gift to Respondents

Respondents will be given $75 for their time, effort and transportation costs. This amount was determined based on what has been the standard and usual level of reimbursement for the target audiences in similar CDC funded activities.

A.10. Assurance of Confidentiality Provided to Respondents

CDC and RTI will take many precautions to secure participants' identifiable information (see Confidentiality section of Consent Form – Attachment 6). The information participants provide during the focus groups will not be linked to the respondents' identities. Participants will use only first names or pseudonyms during the focus group discussions. Transcripts and notes will not include participants' names. The focus group participant questionnaires will be anonymous (i.e. they will not contain any identifying information and will not be linked to individual participants). Audio files of the focus groups will be stored by RTI on a secure share drive and password-protected computers. Additionally, the professional recruitment firm will be required to sign a confidentiality agreement. Reports will not include any identifiable information.

RTI will work with Bernett Research Services, Inc., a recruitment and marketing research agency, to recruit participants for the focus groups. Identifying information (name, address, telephone number, e-mail address) will be used to recruit participants via e-mail or advertisements (e.g. placed in newspapers, Craigslist, and/or other websites) (see Attachment 9 – Recruitment Letter/Advertisement). This information will also be used to send confirmation letters/e-mails and to make reminder calls to respondents (see Attachment 7 – Confirmation Letter). This information will be kept by the recruiting firm separately from any information collected in the focus groups. Screeners will be kept in a locked file cabinet at the recruitment firm or in password-protected computer files. The recruiter will only provide RTI and CDC a summary of participant information on the recruitment grids, which will be stripped of identifiable information, such as the last names, addresses, and telephone numbers of the

participants. The focus group recruiting firm will be instructed to destroy their project-related records at the conclusion of the project.

The precautions taken by CDC and RTI have been evaluated by the Institutional Review Board of RTI and found to be acceptable (see Attachment 8 – RTI IRB approval).

A.11. Justification for Sensitive Questions

Sensitive questions including those concerning alcohol and sexual behavior are necessary when collecting data about alcohol-exposed pregnancies. Respondents will be asked to answer questions regarding their knowledge, attitudes, and behaviors regarding alcohol and alcohol consumption during pregnancy, in addition to questions related to sexual behaviors and contraceptive methods. Participants under the age 21 may provide information about their underage drinking habits.

During the screening process, potential participants will also be told that they will be asked some personal questions, including questions about their sexual behaviors, to see if they qualify for the groups. Verbal consent from the potential participants will be obtained before the potential participants are screened for eligibility over the phone.

The focus groups will be conducted in professional focus group facilities so that RTI note takers can observe the groups from behind a one-way mirror. To ensure participant protection and privacy, we will use consent forms for the focus groups that are approved by RTI's IRB (see Attachment 6 – Consent Form). Once participants arrive at the site of the focus groups, each participant will be escorted to a private room where a member of the project team will conduct the informed consent process. This process will enable the staff member to review the informed consent form with the participant, answer any questions that the participant may have about the project, and collect one initialed copy of the consent form. All participants who agree to participate in the focus groups will be given a copy of the consent form to keep. The consent form will outline the precautions CDC and RTI will take in protecting their information as well as the risks and benefits of participation.

In the event a participant finds any question to be objectionable, the participant can easily skip that question.

Please see Attachment 3 for the Focus Group Guides that features a list of questions asked at the focus groups, Attachment 4 for the Focus Group Participant Questionnaire, and Attachment 5 for the Screening Instrument.

A. 12. Estimates of Annualized Burden Hours and Costs

A. Annualized burden hours are based on the estimated time it will take for potential participants to complete the screener (Attachment 5: 12 minutes) and for eligible participants to complete the consent form (Attachment 6: 5 minutes), participate in the focus group discussion (Attachment 3: 80 minutes), and complete the focus group participant questionnaire (Attachment 4: 10 minutes). The number of respondents for the screener is estimated at 320, since not all of

those who respond to the screener will be eligible to participate. The maximum number of respondents for the completion of the consent form, participation in the focus group discussion, and completion of the questionnaire is 160. Thus, the estimated total annual burden is 317.3 hours.

Table 1: Estimated Annualized Burden Hours

TYPE OF RESPONDENT	FORM NAME	NUMBER OF RESPONDENTS	NUMBER OF RESPONSES PER RESPONDENT	AVERAGE BURDEN PER RESPONSE (in hours)	TOTAL ANNUAL BURDEN (in hours)
Potential Participant	Screening Instrument (Attachment 5)	320	1	12/60	64
Focus Group Participant	Consent Form (Attachment 6)	160	1	5/60	13.3
Focus Group Participant	Focus Group Guides (Attachment 3)	160	1	80/60	213.3
Focus Group Participant	Participant Questionnaire (Attachment 4)	160	1	10/60	26.7
Total					317.3

B. Annualized cost estimates to potential respondents, presented in Table 1, are based on mean (average) hourly wage estimates obtained from the U.S. Department of Labor, Bureau of Labor Statistics at http://www.bls.gov/ocs/. Since these activities will take place in Chicago, IL and Atlanta, GA, average hourly rates in the metro areas of Chicago, IL ($23.18) and Atlanta, GA ($21.16), using the Department of Labor National Compensation Survey-Wages, were averaged to obtain the estimate provided in Table 1 ($22.17). The total number of burden hours for respondents to complete their responses is 317.3 hours. Thus, the total annual respondent cost is $7,034.54.

Table 2: Estimated Annualized Burden Costs

TYPE OF RESPONDENT	NUMBER OF RESPONDENTS	NUMBER OF RESPONSES PER RESPONDENT	AVERAGE BURDEN PER RESPONSE (in hours)	TOTAL ANNUAL BURDEN (in hours)	AVERAGE HOURLY WAGE RATE	TOTAL ANNUAL RESPONDENT COST
Potential Participant	320	1	12/60	64	$22.17	$1,418.88
Focus Group Participant	160	1	95/60	253.3	$22.17	$5,615.66
Total				317.3		$7,034.54

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

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than their time to participate; there are no start-up or maintenance costs. We do not require any additional record keeping.

A. 14. Annualized Cost to the Government

The total cost to the Government for this project is $96,470.

Table 2: Governmental Costs

Expense Type	Expense Explanation	Annual Cost
Government Salaries:	CDC Project Officer: GS-14, 3% time	$ 3,500
	CDC Behavioral Scientist: GS-13, 6% time	$ 5,800
	CDC Behavioral Scientist: GS-13, 6% time	$ 5,800
Travel	To observe conduct of focus groups (Chicago, IL): 2 staff (for 4 days)	$ 3,000
Contractor Costs	For information collection (including travel to Chicago and Atlanta), design, development, printing forms, mailing, editing, transcription, coding, tabulation, analysis and publication of results.	$78,370
	Total Annualized Cost:	$96,470

A. 15. Explanation for Program Changes or Adjustments

This is a new data collection.

A. 16. Plans for Tabulation and Publication and Project Time Schedule

This is a qualitative study using focus groups. Statistical methods will not be used. Participants will also complete focus group participant questionnaires, solely for the general purpose of describing the demographics, alcohol use, and reproductive health behaviors of the groups. This data will not be used for other than descriptive purposes and no identifying information will be collected or disclosed.

Verbatim transcripts, debriefing notes, and digital recordings will be completed for each focus group. The analysis team will review these materials and then analyze them using the following steps (adapted from Krueger & Casey, 2000).

1. Assign each respondent in the group an identification number.
2. Code the responses according to a set of predeveloped codes that represent key theoretical constructs (e.g., knowledge, social support, social norms, etc.).
3. Develop and assign emergent codes for responses that do not fit the pre-existing coding scheme.

4. Using these pre-established and emergent codes, identify the key themes and determine the degree of consensus or discordance with a particular view; the goal of a focus group is to focus on what the group thinks, not on what the individual thinks.
5. In a cross-group matrix, organize the key themes in accordance to the project question most closely addressed by group, noting particularly relevant quotes.
6. Using the cross-group matrix, identify cross-cutting themes and areas lacking consensus.

Project Time Schedule:

OMB Submission	By 10/22/09
Implementation of Focus Groups	Within 4 months following OMB approval
Completion of Focus Groups	Within 6 months following OMB approval
Focus Group Report Manuscript Initial Draft	Within 8 months following OMB approval
Focus Group Report Manuscript Final Draft	Within 10 months following OMB approval
PowerPoint Presentation	Within 10 months following OMB approval

Within 2 months of completion of the focus groups, RTI will prepare and submit to CDC a draft narrative report in the form of an Executive Summary, approximately 20 pages long. The Executive Summary will be organized according to the key questions, and will conclude with recommendations or implications for message development related to alcohol use preconceptionally and during pregnancy. Within 2 weeks of receipt of CDC comments, we will submit a final version of the Executive Summary. RTI will also prepare a draft PowerPoint presentation that will highlight key findings, and offer recommendations for message development; we will submit this to CDC for review within 1 month of the submission of the Executive Summary.

Within 2 months of the end of the focus group data collection, RTI will prepare and submit to CDC for review a manuscript presenting the findings of the three sets of focus groups, approximately 15–20 pages in length. This manuscript will be formatted for submission to a peer-reviewed publication. Within 2 weeks of CDC comments, we will submit a final version of the manuscript.

A. 17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested.

A. 18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

Anderson, J. E., Ebrahaim, S., Floyd, L., & Atrash, H. (2006). Prevalence of risk factors for adverse pregnancy outcomes during pregnancy and the preconception period: United States, 2002–2004. *Maternal and Child Health, 10*, S101-S106.

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Krueger, R. A. & Casey, M. A. (2000). Focus Groups. *A practical guide for applied research* (3rd Ed.). Thousand Oaks, CA: Sage Publications.