**Focus Groups about Cigarette Smoking during Pregnancy and Adverse Outcomes, Including Birth Defects**

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National Center on Birth Defects and Developmental Disabilities
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## A. Justification

### A.1. Circumstances Making the Collection of Information Necessary

Background

According to the Centers for Disease Control and Prevention (CDC), cigarette smoking is the leading cause of preventable morbidity and mortality in the United States (CDC, 2008). In 2007, an estimated 22.4% of women aged 18 to 44 in the United States were smokers (CDC, 2008) and the prevalence of smoking among pregnant women was estimated to be 10.7% (CDC, 2007). In addition, from 2000 to 2004, an estimated 174,000 women in the United States died annually from smoking-attributable causes, and an estimated 776 infants died annually from causes attributed to maternal smoking during pregnancy (CDC, 2008 in Tong et al., 2009).

Several studies have shown that smoking during pregnancy is associated with perinatal complications. Smoking is responsible for 15% of all preterm births, 20%-30% of all low birthweight infants, and 15%-25% of all cases of placental abruption (Andres & Day, 2000). These complications, along with premature rupture of the membranes, are primarily responsible for the 150% increase in perinatal mortality among women who smoke (Andres & Day, 2000). Also, infants of mothers who were heavy smokers (> 25 cigarettes per day) have been found to be four times more likely to have bilateral cleft lip (with or without cleft palate) and twice as likely to have cleft palate with Pierre Robin sequence compared to infants of non-smoking mothers (Honein et al., 2007). Furthermore, secondhand smoke can increase an infant's risk of Sudden Infant Death Syndrome (SIDS), respiratory tract infections (e.g., bronchitis and pneumonia), and ear infections (CDC, 2001, 2004, 2006 in Tong et al., 2009).

Although literature shows that the majority of women are aware that cigarette smoking during pregnancy may be harmful to their unborn children (Dunn, Pirie, & Lando, 1998), some women continue to smoke throughout their pregnancies. This project proposes to look at the knowledge, attitudes, and behaviors of women of childbearing age who smoke and those who used to smoke in order to inform the development of educational messages 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 1.

Overview of the Data Collection System

Data collection for *Focus Groups about Cigarette Smoking during Pregnancy and Adverse Outcomes, Including Birth Defects* will consist of 90-minute discussions, with eight to ten participants in each of the 12 focus groups (see Attachment 2 – Focus Group Guides).

We will focus on four main groups of women:

1. **Female smokers who have never been pregnant:**
   Non-pregnant women of childbearing age (18 to 30 years) who smoke and who are planning a pregnancy within the next year, but who have never been pregnant.

2. **Female smokers who have been pregnant in the past 2 years:**
   Non-pregnant women of childbearing age (18 to 30 years) who smoke, are planning a pregnancy within the next year, and have been pregnant within the past 2 years.

3. **Women who quit smoking during pregnancy:**
   Non-pregnant women of childbearing age (18 to 30 years) who smoked prior to their pregnancy (within the past 2 years) and quit smoking during pregnancy.

4. **Women who *did not* quit smoking during pregnancy:**
   Non-pregnant women of childbearing age (18 to 30 years) who smoked prior to their pregnancy (within the past 2 years) and *did not* quit smoking during pregnancy.

At the end of the discussion, focus group participants will complete a 7-question, paper-and-pencil questionnaire (see Attachment 3 – 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 participants' demographics, such as age and race/ethnicity. Questions about the participants' knowledge, attitudes, and behaviors regarding smoking and pregnancy; questions about graphic warning messages; and general questions about health information predominate.

Notes, discussion transcripts, and questionnaires from the focus groups will not be in an identifiable form. However, the recruitment firms will collect limited information in identifiable form (IIF) through the screener (see Attachment 4 – Screening Instrument) in order to place women in the appropriate focus groups. The recruitment firms will also collect contact information (name, address, e-mail address, telephone number) from focus group participants that will be used to send confirmations or reminders to participants (see Attachment 5 – Confirmation Letter). This information will be kept in secure computer files at the recruitment firms.

## 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, attitudes, and behaviors regarding smoking and its risks to both women and babies during pregnancy. Media, social, and other influences on women's knowledge, attitudes, and behaviors will also be examined. This purpose of the focus groups is

to assist in informing the development of future educational and media efforts to address this serious issue. 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 smoking and reproductive health outcomes?
- What attitudes do women of childbearing age have with regard to smoking and reproductive health outcomes?
- What attitudes do women of childbearing age have with regard to messages about smoking and reproductive health outcomes?
- What kinds of experience do women of childbearing age have with attempting to quit smoking?
- What sources of information (i.e., media, physicians, family, friends, etc.) have provided women with their health knowledge in general and knowledge about smoking and pregnancy specifically? Which of the sources most influence women's knowledge, attitudes, and behaviors? What kinds of information about smoking and pregnancy would women like to receive?

Privacy Impact Assessment Information

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

Identifiable information will be collected by the focus group recruiting firms, 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, knows 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 through the use of Internet and other search engines (such as Google). This project builds on the information found through the literature review, but the information currently available has significant gaps, is outdated, 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 conducting focus groups.

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

The proposed incentive amount for the 90-minute focus groups about cigarette smoking during pregnancy and adverse outcomes is $75 ($50/hour). As explained in the attached letters from our recruitment firms (see Attachment 6 – Recruitment Firm Letters), this amount is necessary in order to recruit women of childbearing age. Sensitive questions, including those concerning

smoking and plans to become pregnant, are necessary when collecting data about smoking and pregnancy. Furthermore, this payment is intended to recognize the time burden placed on the participants, encourage their cooperation, and to convey appreciation for contributing to this important activity. Numerous empirical studies have shown that incentives can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999; Greenbaum, 2000). This level of reimbursement for the target audiences helps to support additional costs participants may incur such as transportation and/or childcare in order to participate. Lower incentives could actually result in higher recruiting costs due to the need to over recruit by higher percentages (Krueger & Casey, 2000).

These focus groups are 90 minutes in length in order to allow for a substantive discussion regarding women's perceptions of cigarette smoking during pregnancy.

**A. 10. Assurance of Confidentiality Provided to Respondents**

CDC and RTI will take many precautions to secure participants' identifiable information (see Attachment 7 – privacy section of Consent Form). 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 privacy agreement. Reports will not include any identifiable information.

Identifying information (name, address, telephone number) will be used to send confirmation letters/e-mails and to make reminder calls to respondents (see Attachment 5 – 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**

Respondents will be asked to answer questions about their knowledge, attitudes, and behaviors regarding smoking in general and smoking during pregnancy. In addition, women will be asked questions related to their quitting and relapse experiences. Sensitive questions including those concerning smoking and plans to become pregnant are necessary when collecting data about smoking during pregnancy.

During the screening process, potential participants will be told that they will be asked some personal questions, including questions about smoking and pregnancy, 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 and other project members 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 have been approved by RTI's IRB (see Attachment 8 – RTI IRB approval). 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 study, 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 2 for the Focus Group Guides that features a list of questions asked at the focus groups, Attachment 3 for the Focus Group Participant Questionnaire, and Attachment 4 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 4: 11 minutes) and for eligible participants to complete the consent form (Attachment 7: 5 minutes), participate in the focus group discussion (Attachment 2: 80 minutes), and complete the focus group participant questionnaire (Attachment 3: 10 minutes). The number of respondents for the screener is estimated at 240, 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 120. Thus, the estimated total annual burden is 234 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 4) | 240 | 1 | 11/60 | 44 |
| Focus Group Participant | Consent Form (Attachment 7) | 120 | 1 | 5/60 | 10 |
| Focus Group Participant | Focus Group Guides (Attachment 2) | 120 | 1 | 80/60 | 160 |
| Focus Group Participant | Participant Questionnaire (Attachment 3) | 120 | 1 | 10/60 | 20 |
| Total | | | | | 234 |

B. Annualized cost estimates to potential respondents, presented in Table 2, are based on mean (average) hourly wage estimates obtained from the U.S. Department of Labor, Bureau of Labor Statistics' National Compensation Survey at http://www.bls.gov/ocs/. Since these activities will take place in Raleigh, NC, Charleston, WV, Chicago, IL, and Phoenix, AZ, average hourly rates in the metro areas or general region of Raleigh, NC, ($20.26), Charleston, WV, ($20.26), Chicago, IL, ($24.94), and Phoenix, AZ ($21.10) were averaged to obtain the estimate provided in Table 2 ($21.64). The total number of burden hours for respondents to complete their responses is 234 hours. Thus, the total annual respondent cost is $5,063.76.

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 | 240 | 1 | 11/60 | 44 | $21.64 | $952.16 |
| Focus Group Participant | 120 | 1 | 95/60 | 190 | $21.64 | $4111.60 |
| Total | | | | 234 | | $5063.76 |

## 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 $81,061.

Table 3: Governmental Costs

| Expense Type | Expense Explanation | Annual Cost |
|---|---|---|
| Government Salaries: | CDC Technical Monitor: GS-15, 2% time | $ 2,637 |
| | CDC Project Officer: GS-14, 3% time | $ 3,500 |
| | CDC Project Consultant: GS-11, 6% time | $ 3,524 |
| Travel | To observe conduct of focus groups (Raleigh, NC, Charleston, WV, Chicago, IL, and Phoenix, AZ ): 2 staff (for 4 days) | $ 7,000 |
| Contractor Costs | For information collection (including travel to Raleigh, Charleston, Chicago, and Phoenix), design, development, printing forms, mailing, editing, transcription, coding, tabulation, analysis and publication of results. | $ 64,400 |
| | **Total Annualized Cost:** | $ 81,061 |

## 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

| | |
|---|---|
| OMB Submission | By 10/23/09 |
| Implementation of Focus Groups | Within 2 months following OMB approval |
| Completion of Focus Groups | Within 5 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 |

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.

All questionnaire items will be compiled and analyzed using descriptive statistics.

Within 3 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 smoking and pregnancy. Within 3 weeks of receipt of CDC comments, RTI 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. RTI 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 from the 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, RTI 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.

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