Supporting Statement A

for

Communication Research on Folic Acid to Support the Division of Birth Defects and Developmental Disabilities

New

January 18, 2012

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Table of Contents

List of Tables

List of Attachments

A. Applicable Laws or Regulations

B. Federal Register Notice

C. Data Collection Instruments

- C1 Screener (in English)
- C2 Screener (in Spanish)
- C3 Informed Consent (in English) - *supplemental*
- C4 Informed Consent (in Spanish) - *supplemental*
- C5 Moderator's Guide (in English)
- C6 Moderator's Guide (in Spanish)

D. IRB Research Determination

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

Background

This is a new Information Collection Request and is authorized by Section 301, "Research and Investigation," of the Public Health Service Act (42 U.S.C. 241) and Sections 304, 306 and 308(d) which discuss authority to maintain data and provide assurances of confidentiality for health research and related activities (42 U.S.C. 242 b, k, and m(d)) (Attachment A). The length of data collection requested for OMB-PRA approval is one year.

Neural tube defects (NTDs) are serious birth defects of the brain (anencephaly) and spine (spina bifida) that affect 3000 pregnancies per year in the U.S (CDC, 2004). Although NTDs can affect any pregnancy, disparities exist with Hispanic women in the U.S. having higher rates of NTD affected births (Williams et al, 2005). Folic acid, a B vitamin, can reduce the risk for many of these NTDs; however, disparities once again exist with Hispanic women having lower levels of folic acid knowledge (Ahluwalia and Daniel, 2001) and consumption (Jasti, Siega-Riz, & Bentley, 2003), than white women. The Prevention Research Team at the Centers for Disease Control and Prevention (CDC), along with many partners, is working toward identifying ways to reduce this disparity, as well as increase folic acid awareness, knowledge, and consumption among all women of childbearing age.

This project will use qualitative focus group methods to examine Hispanic women's knowledge, awareness, and perceptions related to folic acid fortification. The purpose of this data collection activity is consistent with the national research agenda of CDC's Division of Birth Defects and Developmental Disabilities. Additional detail about the need for information for the project is provided below:

Efforts to increase consumption of vitamin supplements containing folic acid among Hispanic women have been ongoing. However, due to differences in diet, many of these women have not benefitted from food fortification to the extent that other race/ethnic groups have. No CDC research currently exists on Hispanic women's knowledge, awareness and behaviors related to foods fortified with folic acid. In an effort to better understand this, it is necessary to conduct focus groups. The focus group sessions will be structured to identify Hispanic women's general awareness and knowledge about folic acid and its role in neural tube defect prevention, general awareness and knowledge about fortification of foods, perceived barriers/motivators to consuming fortified foods, and medium preference for receiving health information.

Privacy Impact Assessment

(i) Overview of the Data Collection System

A telephone screening instrument (Attachments C1-C2) will be used to identify eligible participants. Eligible participants for this project are English and Spanish-speaking women, ages 18-44 years of age, living in the U.S., who identify as Hispanic, who are not pregnant at the time of the focus group.

Eligible participants will be invited to participate in a focus group discussion. Participants will be segmented into groups by age and language preference. An informed consent form in English or Spanish (Attachments C3 and C4) will be given to the participants to sign before the focus group session begins. Focus groups will be used to identify Hispanic women's general awareness and knowledge about folic acid and its role in neural tube defect prevention, general awareness and knowledge about fortification of foods, perceived barriers/motivators to consuming fortified foods, and medium preference for receiving health information. The focus groups will be in English or Spanish and the moderator will be a native-Spanish speaker, fluent in English and with extensive experience in conducting focus group interviews. Because of the size and diversity of the Hispanic populations in Dallas, Texas and Miami Florida, the focus groups will be conducted in these two locations.

(ii) Items of Information to Be Collected

The questions during the focus group discussion will ask participants about what vitamins they feel are particularly important for women, how they choose what foods they eat, and whether they read food labels. It will also identify participants' knowledge about folic acid and its role in birth defects prevention. Finally, the discussion will be used to gather information about participants' general awareness and knowledge about folic acid and its role in neural tube defect prevention, general awareness and knowledge about fortification of foods, perceived barriers/motivators to consuming fortified foods, and medium preference for receiving health information. CDC will not receive any identifiable information.

(iii) Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

No website content directed at children under 13 years of age is involved in this information collection request.

A.2. Purpose and Use of Information Collection

The data collection activities will directly support ongoing efforts within the CDC's Division of Birth Defects and Developmental Disabilities.

Since mandatory folic acid fortification of cereal grain products was mandated in 1998, rates of folic acid-preventable neural tube defects (NTDs) have declined. Disparities in rates remain, however, with NTD prevalence being highest among Hispanic women of childbearing age. Efforts to increase consumption of vitamin supplements containing folic acid among women in this ethnic group have been ongoing, however, due to differences in diet, many of these women have not benefitted from food fortification to the extent that other race/ethnic groups have. Because no research currently exists on Hispanic women's acceptance and attitude of this fortification process, this data collection process provides a way to better understand Hispanic women's understanding of fortification and knowledge about what foods are fortified, perceived barriers/motivators to consuming fortified foods, and how CDC can best include information about fortification in our new and existing educational materials and messages.

Privacy Impact Assessment Information

(i) Why the information is being collected:
The information is being collected to ensure that CDC has accurate and up-to-date information to use to develop messages and materials that include information about folic acid fortification.

(ii) Intended use of the Information:
The findings from the focus groups will be published in the general literature and can be used to ensure that our current materials and website messages are accurate and reflect findings from the research.

(iii) Impact on Privacy to Respondents:
For the purpose of the evaluation, no individually identifiable information is being collected.

A.3. Use of Improved Information Technology and Burden Reduction

This study will not employ automated, electronic, mechanical or other technological data collection techniques for these one-time focus groups with women 18 to 44 years of age who are not pregnant at the time of the focus groups. Participants' use of information technology is not applicable since all data from focus groups and interviews will be collected through interpersonal interactions, not self-administered instruments. Focus groups as a data collection method do not lend themselves to the use of information technology.

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

No similar data are available that meet the needs of the proposed study. No previous research has been conducted with this audience on this topic.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses or other small entities will be involved in this data collection.

A.6. Consequences of Collecting the Information Less Frequently

The consequence of not collecting the information would be that CDC would not have accurate or up-to-date information specific to the target audience on this topic.

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 within 5 CFR 1320.5.

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

A. **Federal Register Notice.** A copy of the Federal Register notice is included as Attachment B. As required by 5 CFR 1320.8(d), a notice of this data collection was published in the Federal Register on March 15, 2011, (volume 76, number 50, pages 14018-14019. No public comments were received in response to the Federal Register Notice.

B. **Efforts to Consult Outside of the Agency**. From December 1, 2009, to January 31, 2010, the following list of representatives from several organizations outside of CDC were consulted and asked to review the data collection instruments for this study.

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

We plan to use a monetary incentive to motivate eligible women to participate in the focus groups. Each participant will receive a $75.00 cash incentive for their time. A substantial body of experimental research indicates that the use of financial incentives assists with recruitment efforts for survey research (Dillman, 2000). Experts in the field of focus group research recommend the use of monetary incentives to encourage individuals to participate in focus group research because they encourage participants to 1) show up for the focus group; 2) show up on time; and 3) hold open the time of the scheduled focus group. Further, offering an incentive communicates to participants that the focus group is important (Krueger and Case, 2000).

We carefully considered the amount of the incentive and concluded that $75.00 (for 1.5 hrs) would encourage women to participate but would not be so great as to be considered an inappropriate influence. We aim to recruit 4-5 women for each of 16 focus groups, or a total of approximately 80 women. Recruitment would be very difficult without such an incentive. Women would be unlikely to schedule the time to travel to the focus group site, potentially incurring costs for transportation and childcare, without a financial incentive. Similar CDC-sponsored focus groups have offered incentives at approximately this level and have found this amount to result in acceptable recruitment rates.

A.10. Assurance of Confidentiality Provided to Respondents

The NCBDDD Privacy Act Coordinator has reviewed this application and has determined that the Privacy Act is not applicable. Respondents will not provide personal information but will be asked about their awareness, knowledge, opinions of food fortification and how they would like to see folic acid information portrayed in a written format.

Names and contact information will not be used after the focus groups have been scheduled, and the personally identifiable information will be deleted no later than 1 year after completion of data collection. Respondents' full names will not be recorded during focus group discussions.

Participants will be reminded verbally and in writing (on the consent form) that their participation is voluntary and that they may choose not to answer a question at any time or may withdraw from the focus group. Should they decide to withdraw from the focus group discussion, they will still receive their cash incentive. Participants will be addressed only by their first names during the focus groups. No other personal identifying information will be collected during the focus groups.

Last names will never be provided to the transcriptionist, the research assistants, or the data analysts. CDC will not use individual names or any identifiable information to publish the final reports; only anonymous or aggregate data will appear in final reports. All information related to the project will be stored in locked filing cabinets. All audio recordings will be permanently erased when the study is over.

<u>IRB Approval</u>

The research protocol was determined to be exempt by the CDC Institutional Review Board (IRB). It was approved on March 4, 2011 by the Institutional Review Board (IRB) at Battelle, the contractor responsible for collecting the data.

<u>Privacy Impact Assessment Information</u>

A. This submission has been reviewed by the NCBDDD Privacy Act Coordinator, who determined that the Privacy Act does not apply.

B. All information (screeners, consent forms, transcripts, and tapes) related to the project will be stored in locked filing cabinets. One year after completion of the study, all audio recordings will be permanently erased. The electronic data files

will be retained on password-protected computers for 5 years after completion of the study. All focus groups will be conducted at a private focus group facility. Results will be presented in aggregate form only. No individual identifying characteristics will be associated with any one participant. Consent form information including the participant's name will be kept separate from the transcripts.

C. We will be asking respondents for written consent. On the day of the focus group, the consent form will be provided to all participants in their chosen language (English or Spanish). Prior to beginning with the focus group questions, the focus group moderator will give an introduction/overview of study and focus group logistics, give all participants an opportunity to ask questions about the study, answer any questions about consent or the study, and collect signed consent forms from participants.

D. Prior to starting the focus group questions, the moderator will review the written consent form to inform respondents about the voluntary nature of this response during the informed consent process. The moderator will emphasize to the respondents that : a) their participation in the focus group is completely voluntary, b) they may choose not to answer questions that they do not want to answer, and c) they may choose to leave the interview at any time for any reason.

A.11. Justification for Sensitive Questions

Topics typically considered to be of a sensitive nature include sexual practices, alcohol or drug use, religious beliefs or affiliations, immigration status, and employment history. No questions regarding these topics or any other topic of a sensitive nature will be asked in this data collection activity.

A.12. Estimates of Annualized Burden Hours and Costs

Annualized Burden Hours. The estimates of annualized burden hours are based on the results of pilot testing, past experience with recruitment, and the administration of similar focus groups.

It is estimated that 320 respondents will have to be screened in order to recruit 80 participants. Each screening will take approximately 6 minutes to complete. The estimated response burden for the screening process is 32 hours.

Each focus group will have an average of 4-5 participants. A total of 16 focus groups will be conducted. Assuming the larger number of participants (5) in each group, a total of 80 participants will be included. Each focus group will last 1.5 hours.

The total estimated burden in hours, including screening and focus group participation, is shown in Table A.12-1. Overall, we estimate the total annual burden for participation in this study to be 152 hours. This request is being submitted to obtain OMB clearance for one (1) year.

Table A.12-1. Estimated *Annualized Burden Hours*

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average burden per response (in hours)	Annual Burden (in hours)
Women 18-44, Hispanic ethnicity; English and Spanish speakers	Screener	320	1	6/60	32
Women 18-44, Hispanic ethnicity; English and Spanish speakers	Focus Group Guide	80	1	1.5	120
Total……		……	……	……	152

Annualized Burden Costs. The estimated cost to respondents for the study is shown in Table A.12 – 2. There are no costs to respondents other than their time to participate. The employment status and actual wages of participants is unknown and will not be collected as part of the study. Wage rate data were obtained from the U.S. Department of Labor, Bureau of Labor Statistics http://data.bls.gov/cgi-bin/surveymost?le. An hourly wage rate of $14.90 was estimated by averaging the median hourly salary for White women ($17.10) and Hispanic women ($12.70) for the year 2010. Using these estimates, the total annualized cost to respondents for the study is $4,529.60 for the 2011-2012 approval period.

Table A.12-2. Estimates of Annualized Cost to Respondents

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Women 18-44, Hispanic ethnicity; English and Spanish speakers	Project One Screener	320	1	6/60	32	$14.90	$476.80
Women 18-44, Hispanic ethnicity; English and Spanish speakers	Project One Focus Group Guide	80	1	1.5	120	$14.90	$1,788.00
Total					152		$2,264.80

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers.

The data collection entails no additional costs to respondents or recordkeepers.

A.14. Annualized Cost to the Federal Government

The total annualized cost to the Government for this project is $135,750 for the data collection approval period. This figure includes contract costs to Battelle, salaries, fringe, and travel related to involvement of 2 FTEs.

Table A.14-1 Annualized Cost to the Federal Government

Expense Type	Expense Explanation	Annualized Costs
Government Salaries	1. CDC Technical Monitor: GS-13, 15% time	$15,500
	2. CDC Project Assistant: GS-13, 5% time	$4,250
Travel	To observe conduct of focus groups (Miami and Dallas): 1 staff per location (for 3-4 days)	$6000
Total Contract Costs	For information collection (including travel to Miami and Dallas), design, development, printing forms, mailing, editing, transcription, coding, tabulation, analysis and finalizing of results.	$110,000
Total Annualized Costs		$135,750

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

A. Tabulation Plan. Data tabulation will involve content analyzing textual data gathered during the focus groups using QSR N6 software. The data analysis plan has been designed to answer the following questions:

Research questions:

1. What foods and vitamins do participants think are important for women's health? For pregnant women or women planning a pregnancy?
2. What do participants know about the role of folic acid in NTD prevention? About the higher risk for NTDs among Hispanic women?
3. What have participants heard (or what do they know) about food fortification?
4. What are participants' perceptions of fortified foods?
5. What are participants' perceived barriers/motivators to consuming fortified foods?
6. What are the preferred mediums of receiving health information for these participants?

First, audio recordings of each focus group will be transcribed in the original language (English or Spanish) by a professional. These transcripts will be uploaded into a QSR N6 database. Electronic versions of handwritten field notes generated during interviews and focus groups will also be uploaded into the database.

Experienced qualitative researchers will then code each paragraph of text using a pre-developed codebook. A hierarchy of codes will be developed for each expected and emergent theme. The coded textual data will then be sorted in order to examine text relating to each of the research questions listed above. Content analysis will be based on matching patterns of observation across multiple focus groups within each site and across sites. The data will be summarized by the key variables identified in the research questions listed above. The data will be summarized primarily in narrative format. Supplementary tables similar in style to Tables A.16-1 and A.16-2 will also be used to summarize the study data.

Table A.16-1. Summary of Textual Data Relating to Awareness, Knowledge, and Behavior related to Foods Fortified with Folic Acid among Hispanic Non-Pregnant Women

Theme	Description of Theme	Illustrative Quotes
Healthy food consumption		
Awareness/knowledge of folic acid fortified products		
Awareness/knowledge of folic acid		
Perceptions of barriers/motivators to consuming fortified foods		
Preference for how to receive health information		

Table A.16-2. Summary of Textual Data Relating to Awareness, Knowledge, and Reactions to Existing Educational Materials.

Theme	Description of Theme	Illustrative Quotes
Role of Folic Acid		
Changes to existing educational materials		
Take-home messages		
Appealing aspects of existing educational materials		
Perceptions of existing educational materials		

B. Publication Plan. Technical reports will be prepared to summarize project activities and the results of the data analysis. The results of the project will be published in the general literature through the publication of manuscripts in peer-reviewed journals and through presentations at professional meetings. Findings might also be used to update new and existing CDC educational materials and website content.

C. Project Timeline. In preparation for requesting OMB clearance, a project planning team consisting of 3 CDC staff (one of whom was a Scimetrika contractor for CDC) and 3 Battelle staff developed and reviewed the screening instruments and focus group moderator guides and prepared translated materials. While the OMB package is undergoing review, focus group facilities to be used in the selected locations will be chosen, and all data collection personnel will be trained. Data collection activities are anticipated to begin immediately following receipt of OMB clearance.

Table A.16-3. Project Time Schedule

Activity	Time Schedule
Submit package to OMB for Approval	March-April 2011
Revise and resubmit OMB package for Approval	December 2011
Recruit focus group participants	Within 1-4 months following OMB approval
Conduct focus groups	Within 2-5 months following OMB approval
Transcription focus group data	Within 3-5 months following OMB approval
Coding of focus group data	Within 6 months following OMB approval
Analysis of focus group data	Within 7-8 months following OMB approval
Write draft report	Within 8 months following OMB approval
Submit final report to CDC	Within 9 months following OMB approval
Presentation of results at professional meeting	Within 18 months following OMB approval

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

No exemption from display of expiration date is requested.

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

No exceptions to certification are sought.