Supporting Statement

for

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

New

July 5, 2011

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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 1) examine the response of women to a proposal to supplement corn masa with folic acid; and 2) examine the response of women to existing CDC folic acid educational materials. Hereafter, we refer to these two purposes as Projects 1 and 2, respectively. The purposes of this data collection activity are consistent with the national research agenda of CDC's Division of Birth Defects and Developmental Disabilities. Additional detail about the need for information for these two projects is provided below:

Project 1: 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. An effort is currently underway to explore the possibility of fortifying corn masa flour, a staple product in many traditional Latino, and in particular Mexican and Central American foods. There is concern about consumer reaction to this fortification. No research currently exists on the consumer's acceptance and attitude of this fortification process. In an effort to better understand consumer acceptance, 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, awareness and knowledge about fortification of cereal grain products, whether fortification of corn masa flour products would change their current reported use of these products, and overall reaction to potential folic acid fortification of these products.

Project 2: A number of CDC's English-language folic acid educational materials currently being used were developed over 10 years ago. Research to determine whether these materials continue

to be appealing and resonate with the target audience is imperative to the success of our folic acid education efforts. The focus group sessions shall be structured to identify women's awareness and knowledge about folic acid, and how they would like to see folic acid information portrayed in a written format.

Privacy Impact Assessment

(i) Overview of the Data Collection System

Project 1: 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 Mexican, Mexican American, or Central American, 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 who report either consuming corn masa flour products less than 4 times or 4 or more times per week. 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 NTD prevention, perception of their risk for having an affected pregnancy, awareness and knowledge about fortification of cereal grain products, whether fortification of corn masa flour products would change their current reported use of these products, and overall reaction to potential folic acid fortification of these products. 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 of the Mexican-American population in Dallas, Texas and the Central American population in Miami Florida, the focus groups will be conducted in these two locations.

Project 2: A telephone screening instrument (Attachment D1) will be used to identify eligible participants. Eligible participants for this project are women 18 to 44 years of age who are English-speakers, not pregnant at the time of the focus groups and do not have a child with a birth defect such as spina bifida or anencephaly. Eligible women will be invited to participate in a focus group discussion. Participants will be segmented into groups based on self-identification as either vitamin users (take a vitamin containing folic acid 4-7 days per week) or non-users (take a vitamin containing folic acid less than 4 days per week) and pregnancy contemplation status.

An informed consent form (Attachment D2) will be given to the participants to sign before the focus group session begins. Focus groups will be used to identify women's awareness and knowledge about folic acid, and how they would like to see folic acid information portrayed in a written format. These groups will be conducted in English only and they will take place in St. Louis, Missouri and Atlanta, Georgia.

(ii) Items of Information to Be Collected

Project 1: 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 partcipants' awareness and knowledge about fortification of cereal grain products, whether fortification of corn masa flour products would change their current reported use of these products, and overall reaction to potential folic acid fortification of these products. CDC will not receive any identifiable information.

Project 2: The questions during the focus group discussion will identify participants' knowledge about folic acid and its role in birth defects prevention, as well as identify their source of information about folic acid. The majority of the discussion will center on participants' reactions to educational materials they are shown, which are currently being used to educate women about folic acid. In particular, they will be asked to identify the main message of the materials, provide feedback about the visual appeal of the materials, and identify what should and should not be changed about the materials. CDC will not receive any identifiable information.

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

Project 1: No website content directed at children under 13 years of age is involved in this information collection request.

Project 2: 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.

Project 1: CDC is offering technical assistance to partners who are working to develop a petition for the fortification of corn masa flour with folic acid. 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 what the level of acceptance of a fortified

product will be, and how best to label a fortified product for this audience. The findings from this formative work will be provided to the partner group, which includes the primary manufacturer of corn masa flour in the U.S. This data collection process is a critical component to the overall success of the petition process, since not knowing what the consumer reaction will be can be detrimental to folic acid fortification efforts. If the data collection yields findings that consumer acceptance is low, the manufacturer can know ahead of time and develop a marketing campaign aimed at educating the audience about the importance of folic acid and the benefits of fortification.

Project 2: A number of CDC's English-language folic acid educational materials currently being used were developed over 10 years ago. This data collection is critical to ensuring that these materials continue to be appealing and resonate with the target audience. Over the past ten years, more than 10 million folic acid materials have been requested by CDC partners, health care professionals, and the general public. These materials are a major avenue for disseminating our important folic acid messages. However, many of the materials are old and there is concern that they are outdated. Audience research is needed to identify whether the audience understands the information in the materials, whether they can relate to the text information and the visuals, and whether they feel they can do what the materials ask them to do. Without this data collection, we cannot continue to improve our folic acid materials to ensure that they are meeting the needs of our target audience.

Privacy Impact Assessment Information

(i) Why the information is being collected:

Project 1: The information is being collected to help inform a larger effort on the part of CDC partners who are submitting a petition to the Food and Drug Administration for approval to fortify corn masa flour with folic acid.

Project 2: The information is being collected to help identify ways to revise our folic acid educational materials to ensure that they continue to be appealing and resonate with the target audience.

(ii) Intended use of the Information:

Project 1: The findings from the focus groups will be provided to CDC partners who are submitting a petition to the Food and Drug Administration for approval to fortify corn masa flour with folic acid.

Project 2: The findings from the focus groups will be used by CDC staff to make revisions and improvements to our existing folic acid educational materials.

(iii) Impact on Privacy to Respondents:

Project 1: For the purpose of the evaluation, no individually identifiable information is being collected.

Project 2: 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.

Project 1: No previous research has been conducted with this audience on this topic.

Project 2: The materials being shown to focus group participants are unique to CDC. No other entities have conducted research on their appeal with the intended audience.

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

Project 1: The consequence of not collecting the information would be that our partners would not have critical data to support the fortification initiative: specifically, audience reaction to fortified corn masa flour. Each respondent will only be asked to participate in one focus group.

Project 2: The consequence of not collecting the information would be that we would not know whether the folic acid educational materials we are widely distributing are understood and appeal to the target audience. Each respondent will only be asked to participate in one focus group.

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 for both Projects 1 and 2. Each participant will receive a $75.00 cash incentive to participate. 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. For each project, we aim to recruit 4-5 women for each of 16 focus

groups, or a total of approximately 160 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 CDC 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 CDC 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. Two versions of data collection forms have been developed for each of the data collection projects (1 and 2). The burden estimate of each version of the instruments is the same.

For each project, 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 per project.

Each focus group will have an average of 4-5 participants. A total of 32 focus groups will be conducted; 16 for each project. Assuming the larger number of participants (5) in each group, a total of 160 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,

including both Project 1 and 2, to be 304 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, Mexican or Central American heritage; English and Spanish speakers	Project One Screener	320	1	6/60	32
Women 18-44, Mexican or Central American heritage; English and Spanish speakers	Project One Focus Group Guide	80	1	1.5	120
Women 18-44 (English speakers)	Project Two Screener	320	1	6/60	32
Women 18-44 (English speakers)	Project Two Focus Group Guide	80	1	1.5	120
Total……		……	……	……	304

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, Mexican or Central American heritage; English and Spanish speakers	Project One Screener	320	1	6/60	32	$14.90	$476.80
Women 18-44, Mexican or Central American heritage; English and Spanish speakers	Project One Focus Group Guide	80	1	1.5	120	$14.90	$1,788.00
Women 18-44 (English-speakers only)	Project two Screener	320	1	6/60	32	$14.90	$476.80
Women 18-44 (English-speakers only)	Project two Focus Group Guide	80	1	1.5	120	$14.90	$1,788.00
T Total		T			3 304		$4,529.60

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 $155,500 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, 30% time	$31,000
	2. CDC Project Assistant: GS-13, 10% time	$8500

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		$155,500

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 for this project will be tabulated separately for Projects 1 and 2. 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 for Project 1:

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? What do they know about corn masa flour fortification and folic acid? What have they heard (or what do they know) about cereal grain products? Corn masa flour?
4. How would fortification of corn masa flour products change their intention to use these products?
5. What words would participants want to see on the label of foods made from corn masa flour fortified with folic acid?

Research questions for Project 2:

1. What do participants know about the role of folic acid in NTD prevention?
1. What do participants like about the existing campaign materials? What do they dislike?
2. What do participants understand are the messages from the folic acid messages?
3. How could existing campaign materials be improved to make them more appealing, relevant, and effective?
4. What are the differences in how women perceive existing campaign materials based on pregnancy readiness or vitamin use?

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 among Mexican or Central American Non-Pregnant Women Who Consume Corn Masa.

Theme	Description of Theme	Illustrative Quotes
Healthy food consumption		
Awareness/knowledge of folic acid fortified products		
Awareness/knowledge of folic acid		
Intensions to use folic acid fortified products		
Product Labels		

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 study will also be disseminated to various stakeholders with an interest in folic acid fortification. For Project 1, the most immediate plan for disseminating results of the study will be to provide them to CDC partners currently working on developing a petition to the Food and Drug Administration to allow the fortification of corn masa flour with folic acid. Results from both projects will also be reported through the publication of manuscripts in peer-reviewed journals and through presentations at professional meetings.

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
Project 1: Recruit focus group participants	Within 1-4 months following OMB approval
Project 1: Conduct focus groups	Within 2-5 months following OMB approval
Project 1: Transcription focus group data	Within 3-5 months following OMB approval
Project 1: Coding of focus group data	Within 6 months following OMB approval
Project 1: Analysis of focus group data	Within 7-8 months following OMB approval
Project 1: Write draft report	Within 8 months following OMB approval
Project 1: Submit final report to CDC	Within 9 months following OMB approval
Project 2: Recruit focus group participants	Within 8 months following OMB approval
Project 2: Conduct focus groups	Within 9 months following OMB approval
Project 2: Transcription focus group data	Within 10 months following OMB approval
Project 2: Coding of focus group data	Within 11 months following OMB approval
Project 2: Analysis of focus group data	Within 12 months following OMB approval
Project 2: Write draft report	Within 13 months following OMB approval
Project 2: Submit final report to CDC	Within 15 months following OMB approval
Project 1 & 2: 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.