Focus Groups Assessing the Uptake and Effectiveness of *Inside Knowledge: Get the Facts About Gynecologic Cancer Campaign* Materials

Generic Information Collection

OMB No. 0920-0800

Supporting Statement Part A

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TABLE OF CONTENTS

Abstract

CDC is requesting approval for an information collection request under a currently approved generic clearance (OMB control number 0920-0800, "Focus Group Testing to Effectively Plan and Tailor Cancer Prevention and Control Communication Campaigns"). Focus groups in racially and ethnically diverse areas in the United States will be held to assess the cultural appropriateness, uptake and effectiveness of *Inside Knowledge: Get the Facts About Gynecologic Cancer Campaign* materials. Information will be collected through focus groups involving the general public and health care providers. Focus groups will be held in nine geographic areas throughout the United States and its associated territories-Alaska, Michigan, New Jersey, Puerto Rico, Tennessee, Texas, West Virginia, Wisconsin, and Yap Pacific Island Jurisdiction, all of which have a high gynecologic cancer burden. The number of focus group sessions and numbers of attendees expected are included in this submission. Discussion group questions and a consent form are also included in this submission. Qualitative findings from this information collection will be used to assess the clarity, salience, appeal, and uptake of current *Inside Knowledge* materials and inform development of new materials.

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), Division of Cancer Prevention and Control (DCPC), submits this new information collection request as part of a previously approved generic clearance (OMB control number 0920-0800, "Focus Groups Assessing the Uptake and Effectiveness *of Inside Knowledge: Get the Facts About Gynecologic Cancer* Campaign Materials"). The information collection for which approval is sought is in accordance with CDC's mission, as described by Section 301 of the Public Health Service Act (PHSA, 42 U.S.C. 242; see Appendix A1).

The prevention and control of gynecologic cancers is an area of emphasis within DCPC. Each year, approximately 81,000 women in the United States are diagnosed with a gynecologic cancer and about 27,000 women die from these diseases (USCS 2010). DCPC conducts awareness activities as specifically authorized by the Gynecologic Cancer Education and Awareness Act of 2005, P.L. 111-324 (Section 247b-17 of the PHSA), also known as Johanna's Law. This legislation was unanimously passed by the U.S. House and Senate (109th Congress) in December of 2006, signed into law by the President in January 2007, and reauthorized in December 2010 under H.R. 2941. A copy of the authorizing legislation is provided in Appendix A2. The reauthorization underscores the continued Congressional priority to increase gynecologic cancer awareness and knowledge among women and health care providers.

CDC received first-time congressionally mandated funding in fiscal year 2006 to develop, implement, and evaluate a national gynecologic cancer awareness campaign, *Inside Knowledge: Get the Facts About Gynecologic Cancer*. A series of focus groups were held to develop and refine campaign messages, assess potential creative concepts, and develop written educational materials (Rim 2011). Materials created to date include fact sheets on each of the five main

gynecologic cancers (cervical, ovarian, uterine, vaginal, vulvar), a comprehensive gynecologic cancer brochure, and gynecologic cancer survivor posters (Rim 2011). All educational materials can be downloaded from the campaign's website www.cdc.gov/cancer/knowledge, and are available in English and Spanish www.cdc.gov/spanish/cancer/knowledge/. These materials educate women and health care providers about the signs and symptoms of, prevention strategies for, and risk factors associated with the five main types of gynecologic cancer. The primary audiences for this initiative consist of women of all ages, races, and ethnicities as well as their primary health care providers.

The central messages of *Inside Knowledge* are—

- There are several types of gynecologic cancers.
- When gynecologic cancers are found early, treatment is most effective.
- Pay attention to your body and know what is normal for you. Gynecologic cancers have warning signs.
- If you notice any unexplained signs or symptoms that last for two weeks or longer, see a doctor right away.
- Get a Pap test regularly to screen for cervical cancer.
- Get the HPV vaccine, if you are 11–26 years old.
- If you are diagnosed with a gynecologic cancer, see a gynecologic oncologist—a doctor who has been trained to treat cancers of a woman's reproductive system.

As mandated by Congress, CDC continues to develop materials to educate women and health care providers about the five main gynecologic cancers, and supports activities to inform future implementation of the *Inside Knowledge* campaign. Such activities require additional focus groups to ensure the campaign products continue to be developed with accuracy, appeal, and overall need. The proposed information collection is consistent with these activities by using focus groups to assess the uptake, saliency, and effectiveness of *Inside Knowledge* materials in nine racially and ethnically diverse U.S. states and affiliated territories with high gynecologic cancer burden. These focus groups extend the initial groups that informed campaign development by specifically targeting areas with diverse populations in order to assess the cultural appropriateness of the existing materials, and collect information that will help guide future development of more specific materials targeted to these populations. Focus groups will be held with the public and with providers in Alaska, Michigan, New Jersey, Puerto Rico, Tennessee, Texas, West Virginia, Wisconsin, and Yap Pacific Island Jurisdiction. All of these areas have a high gynecologic cancer burden, and large populations of underrepresented or underserved individuals. A summary of the racial, ethnic, and socioeconomic characteristics of these areas is in Table A1-A below. An "X" in the column indicates a preponderance of that race, ethnicity or socioeconomic characteristic in the area, and a higher percentage population compared to the U.S. average according to the U.S. Census Bureau (U.S. Census Bureau 2013).

Table A1-A. Racial, Ethnic, and Sociodemographic Characteristics of Focus Group Areas

U.S. State or Affiliated Territory	Race: American Indian or Alaska Native	Race: Asian, or Native Hawaiian or Other Pacific Islander	Race: Black or African American	Ethnicity: Hispanic	Rural Areas	High Poverty
Alaska	X	X			X	
Michigan			X			X
New Jersey		X	X	X		
Puerto Rico				X		X
Tennessee			X		X	X
Texas				X		X
West Virginia					X	X
Wisconsin					X	
Yap		X			X	X

We aim to recruit approximately 600 respondents (400 general public, and 200 health care providers) to participate in focus group discussions. Separate focus groups will be held for each audience segment. Each focus group will be conducted with 10 or fewer respondents. A summary of respondents by State/Territory and audience segment is provided in Table A1-B.

Table A1-B. Number of Respondents by U.S. State or Affiliated Territory and Audience Segment (General Public or Health care providers)

U.S. State or Affiliated Territory	No. of Respondents-General Public	No. of Respondents-Health care providers	Total No. of Respondents	Approximate Number of Focus Groups
Alaska	20	10	30	3
Michigan	50	20	70	7
New Jersey	40	20	60	6
Puerto Rico	50	20	70	7
Tennessee	35	35	70	7
Texas	30	25	55	6
West Virginia	25	10	35	4
Wisconsin	50	40	90	9
Yap	100	20	120	12
Total	400	200	600	61

Data collection efforts for this information collection request will focus on formative evaluation activities, inclusive of gynecologic cancer messages, concepts, and materials testing, similar to the work previously conducted under DCPC's generic clearance (OMB No. 0920-0800). Based on feedback from the proposed focus groups, new materials targeted to the individuals in these areas may be developed, and current materials may be refined.

Overview of the Data Collection System

We will conduct in-person focus group discussions with the general public (N=400) and health care providers (N=200) in selected states and territories. Focus group discussions will be held in-person in small groups ($N \leq 10$), which allows for observation of body language and other subtle cues requiring participants' assembly in one location. Every effort will be made to ensure participation from individuals with diverse demographic characteristics. To that end, staff members from CDC's National Comprehensive Cancer Control Program (NCCCP) (www.cdc.gov/cancer/ncccp) will be asked to participate in identifying and recruiting respondents and facilitating the focus group discussions. The NCCCP was established in 1998, and exists in all U.S. states and many affiliated territories (Major 2009). Each state- or territory-based program in the NCCCP has a unique and demonstrated ability to reach multiple segments of their public and provider populations. These programs also have extensive experience in effectively connecting with individuals in their area, facilitating focus groups, and raising awareness of various cancers (CDC 2012, Stewart 2013).

During focus group sessions, participants will be asked questions at the beginning of the session that specifically relate to the key central messages of the IK campaign (listed above) to ascertain their general knowledge and attitudes toward gynecologic cancer. After a facilitated discussion of IK materials (the five fact sheets available at www.cdc.gov/cancer/knoweldge), questions on appeal, saliency, and understanding of the key central messages will be asked again in order to determine qualitative increases in knowledge and behavioral intentions that are consistent with the key central messages. This qualitative data collection and analysis would determine whether the existing materials are adequate in communicating the key concepts. Along with information collected on saliency and clarity, increases in knowledge at the end of the session would suggest that the materials are appropriate in delivering the key central messages. Persisting deficits in knowledge following the facilitated discussion would indicate that the materials are not clear, or may be culturally inappropriate for the particular audience. It is anticipated that the information collected will lead to refinement of existing materials, and development of new, targeted and more culturally appropriate materials.

Items of Information to be Collected

Focus group discussion questions are designed to assess numerous qualitative dimensions that include, but are not limited to, cancer knowledge, attitudes, beliefs, behavioral intentions, information needs and sources, and knowledge of recommended screening intervals (see Appendix C, Focus Group Discussion Guide). Insights gained from the focus groups will be used to assess whether the existing materials are sufficient and appropriate and will also assist in the development of materials targeted to certain racial and ethnic groups, and/or refinement of

existing campaign materials. Discussions will be tailored to audience segment (general public or health care providers).

CDC will not be privy to names, mailing addresses, telephone numbers or email addresses of any of the focus group participants. All women aged 18 and older are eligible to participate in public focus groups, and all primary care providers who treat women 18 years and older on a regular basis, and are in the following specialties are eligible to participate in the provider focus groups: family practice, general practice, internal medicine, obstetrician/gynecologist, physician assistant, nurse, nurse practitioner. Potential participants will be screened using a recruitment form (Appendix D). No personal identifying information used in the recruitment process will be linked to the data collected in the focus group discussions. Thus, no personal information in identifiable form will be collected by CDC. Every focus group participant will be advised that all information he or she provides during the focus group will be treated in a secure manner and will not be disclosed, unless compelled by law (see Consent Form, Appendix B).

Identification of Web Site(s) and Web Site Content Directed at Children Under 13 Years of Age

No Web-based data collection methods will be used. There is no Web content directed at children under 13 years of age.

A2. Purpose and Use of the Information Collection

The purpose of this clearance request is to continue to conduct formative evaluation activities inclusive of material assessing for the *Inside Knowledge* campaign. Outcomes of these activities include the potential development of specific, targeted, culturally appropriate campaign products in accordance with the knowledge learned, as well as refinement of current materials. Manuscripts describing information obtained from the focus groups will be developed for publication in public health practice, communication and/or other journals.

The information collected will be used by DCPC to tailor existing campaign efforts, and/or develop forthcoming campaign materials in an iterative manner consistent with the Health Communication Process (National Cancer Institute 2002).

Privacy Impact Assessment

CDC will not collect information in identifiable form.

A3. Use of Improved Information Technology and Burden Reduction

Electronic data collection methods have limited applicability to focus groups. However, whenever possible, DCPC staff employ electronic technology to aid in data processing and reporting efficiency.

Efforts have been made to design discussion questions that are easily understandable, not duplicative in nature, least burdensome, and are amenable to processing with electronic technology. In all instances, the number of items posed will be held to the minimum required in order to elicit the necessary formative or materials-testing data.

A4. Efforts to Identify Duplication and Use of Similar Information

Based on a division- and federal-wide review, CDC has determined that the planned data collection efforts do not duplicate any other current or previous data collection efforts related to the *Inside Knowledge* campaign.

A5. Impact on Small Businesses or Other Small Entities

CDC is recruiting participants and facilitating focus groups through its National Comprehensive Cancer Control Program (NCCCP), whose state and territory-based local programs are experienced in carrying out these kinds of activities to ensure little impact on small businesses or entities. All efforts will be carefully planned to minimize the burden on physician practices and other small entities.

A6. Consequences of Collecting the Information Less Frequently

As the health communication process illustrates, formative evaluation is a critical segment of a scientifically sound campaign effort. Formative evaluation, which encompasses material testing activities, is essential to assess appeal, saliency, clarity, cultural appropriateness and readability/understandability. If materials are not assessed, then resources could be expended without necessary attention and preparation paid to the overall communication objective. Forgoing testing can also increase the likelihood of unintended consequences from an irrelevantly perceived message and/or decreased credibility of an organization and/or a Federal health official (Wallendorf, 2001 & Harris-Kojetin et al., 2001). Finally, if materials are not tested with the intended audience, a poor execution strategy could weaken a sound concept. For these reasons, focus groups in the nine selected geographic areas are necessary.

There are no legal obstacles to reducing the burden.

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

There are no special circumstances. The activities outlined in this package fully comply with all guidelines of 5 CFR 1320.5.

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

A8.A Federal Register Notice

As required by 5 CFR 1320.8(d), a notice for public comments was published in the Federal Register on August 17, 2011 (Vol. 76, No. 159, pages 51035-51036). One public comment was received and acknowledged. The comment was not specific to the information collection described in the current request.

A8.B Efforts to Consult Outside the Agency

CDC manages the *Inside Knowledge* campaign. There were no consultations outside the agency pertaining to the current request to conduct focus groups.

A9. Explanation of Any Payment or Gift to Respondents

To assess the need for, and amount of, appropriate incentives, we consulted with staff in the nine NCCCP areas where the focus group discussions will take place. These staff will be responsible for recruitment and focus group facilitation. The incentives that we propose are based on their prior knowledge and experience in effective recruitment and participation in their areas.

For consumer focus groups, we propose to provide each respondent with a $15 gift card redeemable at a local grocery store or coffee shop. This gift card is to show appreciation for their participation and recognizes the effort involved in traveling to the focus group location. The denomination of the gift card is less than the value of cash incentives typically associated with a two-hour public focus group.

We will not offer gift cards as incentives for providers who participate in focus group discussions. The NCCCP has demonstrated capacity to reach and ensure participation of providers by providing continuing medical education credits (CMEs) to provider participants. CDC's NCCCP recognizes that focus groups allow for an educational experience and ultimately add to provider knowledge about the topics presented, therefore the opportunity to earn CMEs will be used as an incentive in the provider focus groups.

A10. Assurance of Confidentiality Provided to Respondents

A. Privacy Act Determination

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) has reviewed this OMB submission and determined that the Privacy Act is not applicable. Respondents will be recruited by the NCCCP local programs in each area through existing partnerships with in-state, non-profit, and community-based organizations.

B. Safeguards

Although respondent contact/demographic information may be used to determine eligibility and to schedule focus group participation, personal identifying information will not be linkable at any

time to response data collected during focus group discussions. A minimum amount of demographic information will be retained in focus group notes for purposes of analysis, but will not be sufficient to identify respondents. Participants will be informed that focus groups will be transcribed, and that information collected will be destroyed after completion of each report on findings. DCPC staff, in conjunction with their contractors (SciMetrika, LLC and ICF Macro) and subcontractors (NCCCP), will analyze the focus group data.

C. Consent

All information provided by respondents will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Informed consent will be obtained from respondents (Appendix B); they do not have to answer questions if they do not want to, their responses will be treated in a secure manner, and they can stop participating at any time. CDC has determined that the proposed activities do not require IRB review and approval.

D. Nature of Participation

Participation in the focus group data collection is a voluntary activity. The voluntary nature of participation is stated in the consent form (Appendix B).

A11. Justification for Sensitive Questions

The majority of questions asked will not be of a highly sensitive nature. However, some respondents (namely the general public) may find thinking about and discussing the disease of cancer unpleasant. A portion of respondents could consider questions about race, ethnicity, or other demographic characteristics to be sensitive, although such questions are unlikely to be highly sensitive. Additionally a portion of respondents may feel uncomfortable answering some questions about their individual cancer experiences, level of disease awareness, and/or adopted preventative behaviors (or lack thereof) associated with cancer. Such questions, if asked, would be necessary for the purposes of a targeted communication campaign and thus to the information collection. To minimize psychological distress, the moderator will inform participants that they do not have to respond to any questions they do not want to answer and they may stop participating at any time.

A12. Estimates of Annualized Burden Hours and Costs

A. DCPC estimates that 400 respondents will be involved in the public focus groups (total estimate from all nine U.S. state and territorial populations); and 200 respondents will be involved in the provider focus groups (total estimate from all nine U.S. state and territorial populations) for a total of 600 respondents. Focus groups for the general public and focus groups for health care providers will be held separately. Since the key messages of the campaign are the same for the public and providers, all focus group discussions will be based on a common group of questions (see Appendix C, Focus Group Discussion Guide) but discussions will be tailored according to the audience (general public or provider). In all cases the burden per response is two hours.

Potential participants will be recruited through standard NCCCP practices which include partnering with in-state, non-profit and community-based organizations to identify general public participants, and partnering with local hospitals and clinical staff to identify provider participants. A recruitment/screening form will be delivered in-person or via telephone to potential participants identified through these partnerships (Appendix D). Based on experience recruiting focus group participants in this way, it is estimated that twice the target number of needed respondents must be screened in order to yield the targeted number of respondents.

The total annualized burden to respondents is 1,240 hours, as summarized in Table A12-A below. The total number of responses is 1,800 and the adjusted average burden per response is 41.33 minutes.

Table A12-A: Estimated Annualized Burden to Respondents

Type of Respondents	Form Name	Number of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
General Public	Recruitment Form	800	1	2/60	27
	Focus Group Guide	400	1	2	800
Health Care Providers	Recruitment Form	400	1	2/60	13
	Focus Group Guide	200	1	2	400
Total		1,800			1,240

B. Approximately 67% of respondents will be members of the general public and 33% of respondents will be health care providers. Table A12-B presents the calculations for cost of respondents' time using two categories of mean hourly wages. Hourly mean wage information is from the U.S. Department of Labor, Bureau of Labor Statistics Web site (http://www.bls.gov/ncs/ncswage.htm#Wage_Tables) specifically originating from the January 2007 National Compensation Survey, Bureau of Labor Statistics. The total estimated annualized respondent cost (including the screening form) is $43,844.

There are no costs to respondents except their time to participate in the focus groups.

Table A12-B: Estimated Annualized Cost to Respondents

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Total Burden (in hours)	Average Hourly Wage Rate	Total Cost
General Public	Recruitment Form	800	1	27	$19.76	$534
	Focus Group Guide	400	1	800	$19.76	$15,808
Health care providers	Recruitment Form	400	1	13	$66.59	$866
	Focus Group Guide	200	1	400	$66.59	$26,636
Total		1,800				$43,844

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

None.

A14. Annualized Cost to the Government

The estimated average annual cost to the Federal government for the proposed focus group activities is $272,750. This figure encompasses the salaries of federal employees to oversee the data collection and contractor fees for recruiting participants to and facilitating focus groups:

Table A14-A Estimated Annualized Cost to the Government

Estimated Annualized Cost to the Government	
Cost Category	Estimated Annualized Cost
Federal employee costs • 5% FTE of 1 GS-14 @ $120,000/yr = $6,000 • 5% FTE of 1 GS-13 @ $95,000/yr = $4,750)	$10,750
Contractual costs for focus group facility rental, focus group moderator, participant recruitment, and information transcription	$262,000
Total	**$272,750**

A15. Explanation for Program Changes or Adjustments

This information collection request is submitted as part of an approved generic clearance. There are no program changes or adjustments.

A16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule

Table A16-1 presents the estimated timeline for conducting focus groups following receipt of OMB clearance. Information will be collected over approximately a 6 month time period and will not exceed the current approved expiration date (11/30/2014).

Table A16-A: Estimated focus group schedule for cancer communication campaigns

Activity	Time Schedule
Focus group recruitment	May – June 2014
Focus group discussions	June – August 2014
Analysis of focus group results (topline reports)	September – October 2014
Report Writing/Recommendations to CDC based on Findings	October – November 2014

Focus group findings will inform campaign planning efforts, provide guidance on efforts to refresh existing materials, and aid in the sound development of new communication products for specific cancer communication initiatives. Additionally, findings will be disseminated through presentations and/or posters at meetings and publications in peer-reviewed journals. All abstracts, poster presentations, and manuscripts will undergo CDC clearance review prior to submission to conferences or journals.

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

The OMB expiration date will be displayed.

A18. Exemptions to Certification for Paperwork Reduction Act Submissions

No certification exemption is being sought.

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