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**Focus Groups Assessing the Uptake and Effectiveness of *Inside Knowledge: Get the Facts About Gynecologic Cancer Campaign Materials***  
**2015/2016 Focus Group Testing with Selected Audiences**

Submitted under OMB No. 0920-0800

**Focus Group Testing to Effectively Plan and Tailor Cancer Prevention and Control  
Communication Campaigns**

Generic Information Collection  
Expiration date December 31, 2017

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Supporting Statement Part A

December 22, 2015

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- A2. Johanna's Law
- B. Consent Form
- C. Focus Group Discussion Guide
- D1. Focus Group Recruitment Form for Hispanic Women
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- E1. Cervical Cancer Fact Sheet
- E2. Uterine Cancer Fact Sheet
- E3. Ovarian Cancer Fact Sheet
- E4. Vaginal and Vulvar Cancer Fact Sheet

- Goal of the study: To assess the cultural appropriateness, uptake and effectiveness of *Inside Knowledge: Get the Facts About Gynecologic Cancer Campaign* materials
- Intended use of the resulting data: 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.
- Methods to be used to collect information: Focus groups will be conducted in English and/or Spanish in seven U.S. cities.
- The subpopulation to be studied: The target population for the *Inside Knowledge: Get the Facts About Gynecologic Cancer Campaign* is women aged 18+. Focus groups will be held in three groups of women, including Hispanic women, low socio-economic status (SES) women, and women with disabilities aged 18+ years.
- How data will be analyzed: Inductive, thematic coding will be used to analyze participant comments.

### **A1. Circumstances Making the Collection of Information Necessary**

The Centers for Disease Control and Prevention (CDC), Division of Cancer Prevention and Control (DCPC), submits a new request titled, “Focus Groups Assessing the Uptake and Effectiveness of *Inside Knowledge: Get the Facts About Gynecologic Cancer Campaign* Materials,” as part of a previously approved generic clearance (OMB control number 0920-0800, “Focus Group Testing to Effectively Plan and Tailor Cancer Prevention and Control Communication Campaigns”). 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 Attachment A1).

The prevention and control of gynecologic cancers is an area of emphasis within DCPC. Each year, approximately 90,000 women in the United States are diagnosed with a gynecologic cancer and about 29,000 women die from these diseases (USCS 2015). 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 Attachment 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](http://www.cdc.gov/cancer/knowledge), and are available in English and Spanish [www.cdc.gov/spanish/cancer/knowledge/](http://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. Focus groups have previously been held in select states and territories for women in the general public. Unpublished findings from these focus groups have shown positive reactions to the campaign materials in terms of appeal and saliency. Knowledge uptake was positive among some women; however, some confusion and uncertainty remained related to ovarian cancer risk factors, screening and prevention for cervical cancer, and genetic screening among some populations of women. Because of this uncertainty, additional focus groups are required to ensure the campaign products continue to be developed and designed with accuracy, appeal, and result in knowledge uptake. 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 three populations of women who have a greater need and who have also demonstrated persistent gaps in the uptake of materials from previous focus groups. Message testing will be conducted with three groups of women that have a high gynecologic cancer burden, low cancer screening rates, and large populations of underrepresented or underserved individuals:

1. Women of low socioeconomic status (SES). Underuse of cervical cancer screening is common among low SES women and over 80% of women with cervical or ovarian cancer in one case management system had an annual income of under \$35,000 (Price 2010, Patient Advocate Foundation 2015).

2. Women with disabilities. Similarly, women with disabilities are less likely to receive cervical cancer screening than those without disabilities (Brown 2015).
3. Hispanic women. Hispanic women are less likely to receive cancer screenings and are more likely to be diagnosed with cancer at a later stage than non-Hispanic women (Klabunde 2012).

Focus groups will be conducted in Washington, D.C, Chicago, IL, Hampton, VA, Phoenix, AZ, Atlanta, GA, Philadelphia, PA, and San Diego, CA. The cities where focus groups will be held were selected because they include substantial populations of women in each of the target populations. Only one city, Washington, D.C., was selected to recruit women with disabilities because it is expected that enough respondents will be able to be recruited from this area and will minimize burden to the public. A summary of the ethnic and socioeconomic characteristics of the women who will be recruited from each of area is in Table A1-A below.

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

U.S. City	Ethnicity: Hispanic	Low SES	Disabilities
Atlanta, GA		X	
Chicago, IL		X	
Hampton, VA		X	
Philadelphia, PA	X		
Phoenix, AZ		X	
San Diego, CA	X		
Washington, DC			X

We aim to recruit approximately 194 respondents 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 socio-demographic characteristic is provided in Table A1-B.

**Table A1-B. Number of Respondents by Socio-demographic characteristic**

Socio-demographic characteristic	No. of Respondents	Approximate Number of Focus Groups
Hispanic Women	24	3
Low SES Women	100	10
Women with Disabilities	70	7
<b>Total</b>	194	20

## **A2. Purpose and Use of the Information Collection**

The purpose of this information collection is to support formative evaluation activities inclusive of materials testing for the *Inside Knowledge* campaign. . Previously held focus groups suggest that some persistent gaps in knowledge remain among certain subgroups of women with respect to risk factors and recommended screening for gynecologic cancers. The information gathered from the proposed activities seeks to further understand these gaps in 3 subpopulations: women of low SES, women with disabilities, and Hispanic women. This qualitative data collection and analysis will help us determine whether the existing materials are adequate in communicating the key concepts and the appeal to specific populations. The materials to be tested are included in this information collection request as Attachments E1, E2, E3, and #4. 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. 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. 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).

## **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**

This data collection will not involve small businesses or 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 three selected sociodemographic groups 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 NCCCP and their partners 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 \$25 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.

#### **A10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

##### *Privacy Act determination*

Respondents will be recruited by a professional market research firm that maintains its own records system. No new records system will be created. The Privacy Act does not apply.

##### *Mechanism used for notice or consent*

Participation in focus groups is voluntary, as explained in the Consent Form provided to participants (see Attachment B). Participants will be informed that focus groups will be video and/or audio-taped and transcribed, that any recordings will be destroyed after completion of each report on findings, and that their names will not be included in the summary of findings provided to CDC. Participants will be informed that participation is voluntary; they do not have to answer questions if they do not want to, and they can stop participating at any time.

##### *Extent to which data collection will be identifiable*

Activities do not involve the collection of individually identifiable information. Information will be collected by contractors on CDC's behalf. We do not plan to allow anyone outside of this project to listen to, watch, or read anything that is recorded. The identifiable information needed for recruitment and scheduling purposes will be maintained in the contractor's proprietary record system. CDC will not be privy to names, mailing addresses, telephone numbers or email addresses of any focus group participants. Thus, no personal information in identifiable form will be collected by CDC. CDC will receive a summary report of findings but no identifiable information about focus group participants will be included in the written notes and summaries.

We will audio and video record focus group discussions and transcribe information. The information will be kept in a locked cabinet. We plan to destroy all the information following analysis.

#### **A11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

##### *IRB Approval*

IRB approval is not required for this project because it is public health practice.

### *Sensitive Questions*

The majority of questions asked will not be of a highly sensitive nature. However, some respondents 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 194 respondents will be involved in the focus groups. Since the key messages of the campaign are the same for the populations, all focus group discussions will be based on a common group of questions (see Attachment C, Focus Group Discussion Guide). In all cases the burden per response is two hours.

Potential participants will be recruited through standard NCCCP and partner practices which include partnering with in-state, non-profit and community-based organizations to identify general public participants in each of the target populations. A recruitment/screening form will be administered in-person or via telephone to potential participants identified through these partnerships. Different versions of the screening form will be used for each target audience (see Attachments D1, D2, and D3). 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 402 hours, as summarized in Table A12-A below. The total number of responses is 582 and the adjusted average burden per response is 41.44 minutes.

**Table A12-A: Estimated Annualized Burden to Respondents**

<b>Type of Respondent</b>	<b>Form Name</b>	<b>Number of Respondents</b>	<b>No. of Responses per Respondent</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden (in hours)</b>
Hispanic Women aged ≥18 years	Recruitment Form for Hispanic Women	48	1	2/60	2
	Focus Group Guide	24	1	2	48
Low SES women aged ≥18 years	Recruitment Form for Low SES Women	200	1	2/60	7
	Focus Group Guide	100	1	2	200
Women with disabilities aged ≥18 years	Recruitment Form for Women with Disabilities	140	1	2/60	5
	Focus Group Guide	70	1	2	140
	<b>Total</b>	582			402

B. Table A12-B presents the calculations for cost of respondents' time using two 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/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)) specifically originating from the Occupational Employment Statistics May 2014 National Occupational Employment and Wage Estimates, United States, Bureau of Labor Statistics. The total estimated annualized respondent cost (including the screening form) is \$9,137.

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 Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Total Burden (in hours)	Average Hourly Wage Rate	Total Cost
Hispanic Women aged ≥18 years	Recruitment Form for Hispanic Women	48	2	2	\$22.71	\$45
	Focus Group Guide	24	1	48	\$22.71	\$1,098
Low SES women aged ≥18 years	Recruitment Form for Low SES Women	200	1	7	\$22.71	\$159
	Focus Group Guide	100	1	200	\$22.71	\$4,542
Women with disabilities aged ≥18 years	Recruitment Form for Women with Disabilities	140	1	5	\$22.71	\$114
	Focus Group Guide	70	1	140	\$22.71	\$3,179
	<b>Total</b>	582		402		\$9,137

**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 \$165,750. 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

<b>Estimated Annualized Cost to the Government</b>	
<b>Cost Category</b>	<b>Estimated Annualized Cost</b>
Federal employee costs <ul style="list-style-type: none"> <li>• 5% FTE of 1 GS-14 @ \$130,000/yr = \$6,500</li> <li>• 15% FTE of 1 GS-12 @ \$75,000/yr = \$11,250)</li> </ul>	\$17,750
Contractual costs for focus group facility rental, focus group moderator, participant recruitment, and information transcription	\$148,000
<b>Total</b>	<b>\$165,750</b>

***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 (12/31/2017).

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

<b>Activity</b>	<b>Time Schedule</b>
Focus group recruitment	January - March 2016
Focus group discussions	April – June 2016
Analysis of focus group results (topline reports)	July – August 2016
Report Writing/Recommendations to CDC based on Findings	August – September 2016

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***

There are no exceptions to the certification.

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