Information Collection Request

GenIC Request to Use Generic ICR 0920-1154

CDC's Inside Knowledge Campaign: 2018 Focus Group Research and Testing with the General Public and Hispanic Audiences

Supporting Statement Part A

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- Goal of the study: To conduct formative research examining women's knowledge, attitudes, and behaviors related to the five main gynecologic cancers—cervical, ovarian, uterine, vaginal, and vulvar; and to assess *Inside Knowledge: Get the Facts About Gynecologic Cancer* campaign messages and creative concepts for use in public service advertisements to raise awareness about the signs, symptoms, risk factors, and prevention strategies related to gynecologic cancers.
- Intended use of the resulting data: Findings will help CDC's *Inside Knowledge* campaign managers fine-tune messaging; avoid unintended consequences of untested messages and materials; and ensure that the most effective advertisements are produced and disseminated.
- Methods to be used to collect information: Focus groups will be conducted in English and Spanish in four U.S. cities.
- The subpopulation to be studied: The target population for the *Inside Knowledge* campaign is women ages 35 to 65 years. Focus group participants will be women ages 35-65 years.
- How data will be analyzed: Inductive, thematic coding will be used to analyze participant comments.

The Centers for Disease Control and Prevention's (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 0920-1154) to conduct focus groups to support the *Inside Knowledge: Get the Facts About Gynecologic Cancer* campaign. 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).

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

In January 2007, the Gynecologic Cancer Education and Awareness Act of 2005 was signed into law, authorizing CDC, in collaboration with the U.S. Department of Health and Human Services' Office on Women's Health, to develop the *Inside Knowledge: Get the Facts About Gynecologic Cancer* campaign (www.cdc.gov/cancer/knowledge). This national multimedia initiative raises awareness among women and health care providers about the signs, symptoms, risk factors, and prevention strategies related to the five main gynecologic cancers—cervical, ovarian, uterine, vaginal, and vulvar. *Inside Knowledge* campaign messages were developed based on an extensive review of the scientific literature, consultation with gynecologic cancer experts, and quantitative and qualitative research with health care providers and women. *Inside Knowledge* emphasizes these key messages:

- Pay attention to your body and know what is normal for you. Gynecologic cancers have warning signs.
- When gynecologic cancers are found early, treatment can be most effective.
- If you have vaginal bleeding that is unusual for you because of when it occurs or how heavy it is, see a doctor right away.
- If you notice any other unexplained signs or symptoms that last for 2 weeks or longer, see a doctor.
- Get a Pap test regularly to screen for cervical cancer.
- Cervical cancer is the only gynecologic cancer for which screening is recommended.

- Consider getting the human papillomavirus (HPV) vaccine if you are in the age group for which it is recommended.

To disseminate these messages to women at the community level, CDC developed a wide range of *Inside Knowledge* materials, including symptoms diaries, fact sheets, brochures, and posters. *Inside Knowledge* materials are developed using the four-stage Health Communication Process endorsed by the U.S. Department of Health and Human Services (National Cancer Institute, 2002; Cooper, Gelb, & Chu, 2014; Rim, Polonec, Stewart, & Gelb, 2011). Materials are available to campaign partners through the *Inside Knowledge* web site (www.cdc.gov/cancer/knowledge), which includes educational, scientific, and technical resources that can be downloaded and/or ordered for use in communities, medical practices, and other settings. Currently available campaign materials include English and Spanish television, radio, and digital public service announcements (PSAs); print and digital advertisements, posters, fact sheets and brochures; out-of-home displays (e.g., in transit stations, shopping malls, elevators); and print and digital advertisements and news articles.

The web site also serves as a resource for health educators, health care providers, state and local organizations, and others interested in gynecologic cancer. *Inside Knowledge* materials were developed after CDC conducted multiple rounds of focus groups to assess beliefs, attitudes, and knowledge about gynecologic cancer, and to test creative concepts and approaches among the general public and health care providers. The focus groups enabled CDC to more effectively design, produce, and disseminate gynecologic cancer educational materials and information for the public and for health care providers.

Current campaign priorities include periodically developing new English and Spanish print, digital, and broadcast PSAs. This process requires additional focus group testing of creative concepts and approaches to assess their appeal and whether they are sufficiently motivating to the campaign's target audiences.

CDC plans to conduct 32 in-person focus groups in 2018: 16 focus groups in English: four (4) per city in Boston, Chicago, Los Angeles, and Miami, and 16 focus groups in Spanish: four (4) per city in Chicago, Houston, Los Angeles, and Miami. A maximum of nine women ages 35-65 will participate in each group, resulting in an estimated total of 288 focus group respondents in four cities (9 respondents/group x 32 groups = 288 respondents).

Table A1-A. Study Design

Focus Group Location	Number of Focus Groups in English	Number of Focus Groups in Spanish
Boston, Massachusetts	4	--
Chicago, Illinois	4	4
Houston, Texas	--	4
Los Angeles, California	4	4
Miami, Florida	4	4
Total	16	16

Respondents in the groups will be asked to consider several creative concepts for new television and print PSAs to determine whether they present clear, understandable information that is appealing and sufficiently motivating to raise awareness of the signs, symptoms, risks, and prevention strategies of gynecologic cancers. Materials will be refined based upon focus group participant feedback. Details about the materials to be tested are included in Attachment 4, Creative Concepts Brief. The creative concepts that are culturally relevant to Hispanic women will be translated and adapted into Spanish prior to the focus groups, for testing among Spanish-speakers.

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.

2. Purpose and Use of the Information Collection

The purpose of this information collection is to continue to conduct formative evaluation activities inclusive of materials testing for the *Inside Knowledge* campaign. Focus group respondents will be asked questions that allow CDC to assess their knowledge, attitudes, and behaviors related to gynecologic cancers and to provide feedback and opinions about proposed PSA creative concepts and approaches. Outcomes include development of specific, targeted, culturally appropriate campaign products in accordance with the focus group findings, as well as refinement of current materials. The information collected will be used by DCPC to tailor existing campaign efforts, and develop new campaign materials in an iterative manner consistent with the Health Communication Process (National Cancer Institute 2002). CDC may also develop manuscripts for publication, to describe the process used to develop, implement, and assess the campaign, and the iterative process used that enables CDC to select the most relevant and salient messages and concepts for development into public service advertisements and other materials. Limitations will be noted, including that as with all focus group studies, the findings will not be generalizable and should not be projected beyond the individuals who take part in the study and will not make claims about what women in various demographic categories know, think, or feel.

3. Use of Improved Information Technology and Burden Reduction

Whenever possible, DCPC staff use electronic technology to aid in data processing and reporting efficiency. However, electronic information collection methods are not applicable to the semi-structured discussion format utilized in qualitative focus group testing.

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

4. 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 information collection efforts related to the *Inside Knowledge* campaign.

5. Impact on Small Businesses or Other Small Entities

Respondents will be individual persons. There is no impact on small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

As described in the Health Communication Process (National Cancer Institute 2002), 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 a message that is not perceived as relevant, and/or decreased credibility of an organization and/or a Federal health official (Wallendorf, 2001; Harris-Kojetin, McCormack, Jael, Sangl, & Garfinkel, 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 selected geographic areas are necessary.

There are no legal obstacles to reducing the burden.

7. 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.

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

Part A: PUBLIC NOTICE
As required by 5 CFR 1320.8(d), a notice for public comments was published in the Federal Register on July 18, 2016 (Vol. 81, No. 137, pages 46680-46682). No public comments were received. The current submission does not require publication of an additional Federal Register Notice.

Part B: CONSULTATION
CDC manages the *Inside Knowledge* campaign. There was no consultation outside of CDC with any individuals who are not contractors or subcontractors involved in developing this project.

9. Explanation of Any Token of Appreciation to Respondents

Level of Token of Appreciation

In past focus groups and for the currently proposed focus groups, respondents are required to travel to the focus group facility and participate in the group for 120 minutes. Providing each respondent with a token of appreciation in the amount of $75 helps to show appreciation for her effort and participation. Such modest tokens of appreciation have also been shown to aid in recruitment and boost response rates.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

Overview of the Information Collection

Information collection and analysis will be conducted by contractors who specialize in health communications and marketing. The contractor will recruit respondents to participate in in-person focus group discussions that will be led by a professional moderator and attended by a notetaker. Inductive thematic coding techniques will be used to analyze participant comments and identify themes. The contractor(s) will submit to CDC a de-identified summary report of findings. No information in identifiable form (IIF) will be transmitted to CDC.

Items of Information to be Collected

The target audience for this message development and testing activity is non-incarcerated, non-institutionalized women ages 35-65 years.

The recruitment and screening process is designed to identify respondents who are in the target age range; speak English or Spanish; with the exception of skin cancer, have not been previously diagnosed with any kind of cancer, including gynecologic cancer; have not had a hysterectomy; do not have more than one close female friend or family member that has been diagnosed with any cancer (except skin cancer). Additional demographic questions are designed to ensure that focus groups include a mix of respondents.

Recruiters will ask respondents a limited number of questions for information only, such as: whether they have health insurance. This question has often been used by CDC in focus group recruitment, to help CDC understand the effects of health insurance status on women's personal history of having recommended screening tests. Prospective participants in focus groups will be given the option to not answer this question.

During focus group discussions, respondents will discuss their knowledge, attitudes and beliefs about topics relating to gynecologic cancers, and provide feedback on the messages and materials to be tested. This information is needed to assess the salience and appeal of materials designed to promote awareness of gynecologic cancer risks, symptoms, and prevention strategies.

How Information will be Shared and for What Purpose

Information will be collected by contractors on CDC's behalf. Discussions will also be audio- and video-taped. We will not allow anyone outside of this project to listen to, watch, or read anything that is recorded. The identifiable information needed for 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 respondents. 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 respondents will be included in the written notes and summaries.

Impact on the Respondent's Privacy

None. No personal identifying information used in the recruitment process will be linked to the information collected in the focus group discussions.

Nature of response and opportunities to consent to sharing and submission of information
Participation in focus groups is voluntary, as explained in the Consent Form provided to respondents (see Attachment 3a [English] and Attachment 3b [Spanish]). Respondents will be informed that focus groups will be video- and 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. Respondents 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.

How the Information will be Secured

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

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.

11. Institutional Review Board (IRB) and Justification for 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 experiences, level of disease awareness, and/or adopted preventive 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 discomfort, the moderator will inform respondents that they do not have to respond to any questions they do not want to answer and they may stop participating at any time.

12. Estimates of Annualized Burden Hours and Costs

We estimate that 288 respondents will be involved in the proposed English- and Spanish-language focus groups. In all cases, the burden per response is two hours. The Focus Group Discussion Guide is included as Attachment 1a (English) and Attachment 1b (Spanish).

Potential respondents will be recruited using public information through a combination of sources, including proprietary lists maintained by focus group facilities and professional focus group recruiting agents. A Screening and Recruitment Form will be delivered in-person or via telephone to potential respondents identified through these partnerships (see Attachment 2a for the English language version and Attachment 2b for the Spanish language version).

Based on experience recruiting focus group respondents 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 720 hours, as summarized in Table 12a below.

Table 12a. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours
General Public	Screening and Recruitment Form	576	1	15/60	144
Women aged 35-65 years	Focus Group Discussion Guide	288	1	2	576
Total					720

Table 12b presents the calculations for , of respondents' time using average hourly wage information two categories of mean hourly wages.
Average hourly earnings information from the U.S. Department of Labor, Bureau of Labor Statistics Web site http://www.bls.gov/eag/eag.us.htm for April 2017 was used in the table.
The total estimated annualized respondent cost (including the screening form) is $18,820.80.
There are no costs to respondents except their time to participate in the focus groups.

Table 12b. Annualized Cost to Respondents

Type of Respondents	Form Name	Number of Respondents	Total Burden (in Hours)	Average Hourly Wage	Total Cost
General Public	Screening and Recruitment Form	576	144	$26.14	$3,764.16
Women aged 35-65 years	Focus Group Discussion Guide	288	576	$26.14	$15,056.64
Total		864	720		$18,820.80

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
None.

14. Annualized Cost to the Federal Government

The estimated average annual cost to the Federal government for the proposed focus group activities is $259,700. This figure encompasses the salaries of federal employees to oversee the data collection and contractor fees for recruiting respondents to and facilitating focus groups:

Table A14-A. Estimated Annualized Federal Government Cost Distribution

Cost Category	Estimated Annualized Cost
Federal employee costs • 10% FTE of 1 GS-13 @ $117,000/yr = $11,700	$11,700
Contractual costs for focus group facility rental, focus group moderator, participant recruitment, and information transcription	$248,000
Total	**$259,700**

15. 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.

16. Plans for Tabulation and Publication and Project Time Schedule

Table A16-A presents the estimated timeline for conducting focus groups following receipt of OMB clearance. Information will be collected over approximately a 5-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

Project Time Schedule	
Activity	**Time Schedule**
Focus group recruitment	Upon receiving approval from OMB, tentatively set for January-February 2018
Focus group discussions	February 2018 – June 2018
Analysis of focus group results (topline reports)	February 2018 – July 2018
Report Writing/Recommendations to CDC based on Findings	February 2018 – July 2018

Focus group findings will inform campaign planning efforts, provide guidance on efforts to update and 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 articles in peer-reviewed journals. All abstracts, poster presentations, and manuscripts will undergo CDC clearance review prior to submission to conferences or journals.

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

REFERENCES

Centers for Disease Control and Prevention (2017, February 10). Inside Knowledge: Get the Facts About Gynecologic Cancer Campaign. Retrieved from. www.cdc.gov/cancer/knowledge/.

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