Focus Group Testing to Effectively Plan and Tailor a Young Women and Breast Cancer Communication Campaign

Generic Information Collection
OMB No. 0920-0800
Expiration Date 10/31/2021

Supporting Statement Part A

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TABLE OF CONTENTS

List of Tables

List of Attachments

Attachment A. Legislative Authority – EARLY Act Reauthorization
Attachment B1. Discussion Guide for Focus Groups with Hispanic Young Women (With a Family History of Breast Cancer), English
Attachment B2. Discussion Guide for Focus Groups with Hispanic Young Women (With a Family History of Breast Cancer), Spanish
Attachment B3. Discussion Guide for Focus Groups with Hispanic Young Women (With No Family History of Breast Cancer), English
Attachment B4. Discussion Guide for Focus Groups with Hispanic Young Women (With No Family History of Breast Cancer), Spanish
Attachment B5. Materials for Testing with Hispanic Young Women, English
Attachment B6. Materials for Testing with Hispanic Young Women, Spanish
Attachment C1. Discussion Guide for Focus Groups with African American Young Women (With a Family History of Breast Cancer)
Attachment C2. Discussion Guide for Focus Groups with African American Young Women (Without Family History of Breast Cancer)
Attachment C3. Materials for Testing with African American Young Women
Attachment D1. Discussion Guide for Focus Groups with American Indian/Alaska Native Young Women (With a Family History of Breast Cancer)
Attachment D2. Discussion Guide for Focus Groups with American Indian/Alaska Native Young Women (With No Family History of Breast Cancer)
Attachment D3. Materials for Testing with American Indian/Alaska Native Young Women
Attachment E1. Screening Instrument for Hispanic Young Women (English)
Attachment E2. Screening Instrument for Hispanic Young Women (Spanish)
Attachment F. Screening Instrument for African American Young Women
Attachment G. Screening Instrument for American Indian/Alaska Native Young Women
Attachment H1. Participant Information Sheet, English
Attachment H2. Participant Information Sheet, Spanish

- The goal of this information collection is to conduct focus groups in racially and ethnically diverse areas in the United States in order to assess the knowledge, attitudes, and beliefs of young women regarding breast cancer.
- The resulting data will be used to inform development of campaign components (concepts, messages, and materials) to assure they will motivate young women, both those with average risk and those at an increased risk for developing breast cancer, to respond to calls to action and engage with the campaign.
- Information will be collected from small, in-person focus groups. Each group will have eight (8) to nine (9) participants and is expected to last ninety (90) minutes. All focus groups will be led by a professional moderator using a discussion guide.
- The subpopulations to be studied are:
    - 12 groups of Hispanic women (either aged 18-29 or 30-44; either with or without family history of breast/ovarian cancer);
    - 6 groups of African American women (either aged 18-29 or 30-44; either with or without family history of breast/ovarian cancer); and
    - 4 groups of American Indian/Alaska Native women (either aged 18-29 or 30-44; either with or without family history of breast/ovarian cancer).
- Transcripts of the focus groups will be analyzed using conventional content analysis. This approach allows categories and ultimately themes within the data to be discerned. Informed by the study questions and based on trends identified through the coding process, key themes in the data will be identified.

ABSTRACT

CDC is requesting approval for an information collection request under a currently approved generic clearance (OMB control number 0920-0800, "Focus Group Testing for Cancer Prevention and Control"). Focus groups in racially and ethnically diverse areas in the United States will be held to assess the knowledge, attitudes, and beliefs of underserved young women regarding breast cancer. Like colorectal and gynecologic cancers, breast cancer risk factors also include family history, an important area of exploration for this information collection. Information will be collected through focus groups involving underserved women under the age of 45. 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 knowledge, attitudes, and beliefs of underserved young women regarding breast cancer to inform development of new materials as well as test draft campaign materials.

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The information collection for which approval is sought is in accordance with CDC's mission to conduct, support, and promote efforts to prevent cancer, reduce its risk, increase early detection and better treatment, and improve the quality of life for cancer survivors authorized by Section 301 of the Public Health Service Act (PHSA, 42 U.S.C. 241).

CDC requests the proposed data collection be conducted using the Generic Information Collection mechanism of Focus Group Testing for Cancer Prevention and Control, OMB No. 0920-0800. The respondent universe for this data collection aligns with that approved under OMB 0920-0800.

Approximately 11% of all breast cancer cases in the United States occur in women under 45 years of age. Occurrences of breast cancer among these women are often accompanied by higher risks of recurrence and death, compared to older women with the disease. These women also face unique and significant long-term, treatment-related side effects such as infertility, cognitive dysfunction, muscular and skeletal issues, and cardiac and vascular concerns. They are also at an increased risk for developing new cancers and other co-morbid conditions.

In 2009, Congress established the Education and Awareness Requires Learning Young (EARLY) Act, section 10413 of the Patient Protection and Affordable Care Act (Public Law 111-148). The EARLY Act legislation specified the need to create an education and outreach campaign to highlight the breast cancer risks facing young women and women of higher-risk ethnic and racial backgrounds, while empowering them with the tools they need to fight the disease. In 2014, Congress reauthorized this legislation (Attachment A – Legislative Authority), re-emphasizing the importance of educating young women about breast health and breast cancer risk.

In response, the Division of Cancer Prevention and Control (DCPC) developed a campaign, *Bring Your Brave,* to increase knowledge of breast health and breast cancer among women,

particularly among those under the age of 45 and those at heightened risk for developing the disease. These initiatives, which are branded under a campaign name and logo, include web and social media content, videos, fact sheets, and digital media advertisements. CDC is expanding and refining messaging and materials for its audiences for the *Bring Your Brave* campaign.

We aim to recruit approximately 198 respondents (108 Hispanic women aged 18–44; 54 African American, non-Hispanic women aged 18–44; and 36 American Indian/Alaska Native, non-Hispanic women aged 18–44) to participate in focus group discussions. Separate focus groups will be held for each audience segment. Each focus group will be conducted with nine (9) or fewer respondents. A summary of respondents by audience segment is provided in Table A1-A through A1-C.

Table A1-A. Hispanic Young Women Respondents

Hispanic Young Women Respondents								
	With a family history of breast or ovarian cancer				**With no family history of breast or ovarian cancer**			
	Los Angeles, CA	San Antonio, TX	Atlanta, GA	Chicago, IL	Chicago, IL	San Antonio, TX	Los Angeles, CA	Atlanta, GA
Age 18–29	1 group Spanish	1 group	-	-	1 group	1 group Spanish	1 group	1 group
Age 30–44	1 group	1 group Spanish	1 group	1 group	-	1 group	1 group Spanish	-
Total Groups	6 groups with a family history, 2 groups age 18–29, 4 groups age 30–44, 2 groups in Spanish				6 groups without a family history, 6 groups age 18–29, 2 group age 30–44, 2 groups in Spanish			
Inclusion Criteria	Include mix of • income levels • education levels (limit 1 PhD or JD per group) • marital status • child status • have/have not undergone genetic testing for BRCA gene mutation, including direct-to-consumer testing							
Exclusion Criteria	Exclude women who • are breast or ovarian cancer survivors • work in a healthcare field or live with a healthcare provider • do not use the internet at least 2 hours each week • do not own a smart phone							

Table A1-B. African American Young Women Respondents

African American Young Women Respondents						
	With a family history of breast or ovarian cancer			**With no family history of breast or ovarian cancer**		
	Los Angeles, CA	Chicago, IL	Jackson, MS	Los Angeles, CA	Chicago, IL	Jackson, MS
Age 18–29	-	1 group	-	1 group	-	1 group
Age 30–44	1 group	-	1 group	-	1 group	-
Total Groups	3 groups with a family history, 1 group ages 18–29, 2 groups ages 30–44			3 groups without a family history, 2 group ages 18–29, 1 groups ages 30–44		
Inclusion Criteria	Include mix of • income levels • education levels (limit 1 PhD or JD per group) • marital status • child status • have/have not undergone genetic testing for BRCA gene mutation, including direct-to-consumer testing					
Exclusion Criteria	Exclude women who • are breast or ovarian cancer survivors • work in a healthcare field or live with a healthcare provider • do not use the internet at least 2 hours each week • do not own a smart phone					

Table A1-C: American Indian/Alaska Native Young Women Respondents

American Indian/Alaska Native Young Women Respondents				
	With a family history of breast or ovarian cancer		**With no family history of breast or ovarian cancer**	
	Philadelphia, MS	Tulsa, OK	Philadelphia, MS	Tulsa, OK
Age 18–29	-	1 group	1 group	-
Age 30–44	1 group	-	-	1 group
Total Groups	2 groups with a family history, 1 of		2 group without a family history, 1 of	

	each age range	each age range
Inclusion Criteria	Include mix of • income levels • education levels (limit 1 PhD or JD per group) • marital status • child status • have/have not undergone genetic testing for BRCA gene mutation, including direct-to-consumer testing	
Exclusion Criteria	Exclude women who • are breast or ovarian cancer survivors • work in a healthcare field or live with a healthcare provider • do not use the internet at least 2 hours each week • do not own a smart phone	

The purpose of this information collection is to determine if the campaign materials under development will motivate women — those with average and increased risk of developing breast cancer — to respond to the calls to action and engage with the campaign. Information on the tone, feel, and content that would most appeal to these women is needed to guide the development of campaign materials.

Spanish language groups will also help CDC determine the cultural differences and adaptation needs for Spanish-speaking women.

A1.A Overview of the Data Collection System

Small, in-person groups ($N \leq 10$), allow for observation of body language and other subtle cues requiring participants' assembly in one location. Each group will have eight (8) to nine (9) participants and is expected to last 90 minutes. All focus groups will be led by a professional moderator selected by CDC DCPC. Up to three observers will observe the focus groups in-person. Additionally, up to five invited observers may view the focus groups via online streaming. The focus groups will be digitally recorded (audio recording) and transcripts will be prepared from these recordings.

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 young women and breast cancer campaign to ascertain their general knowledge and attitudes toward breast cancer. After a facilitated discussion of two campaign materials, 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. 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.

A1.B Items of Information to be Collected

The focus groups will assess numerous qualitative dimensions that include, but are not limited to, breast cancer knowledge, attitudes, beliefs, behavioral intentions, information needs and sources. Focus groups will also assess key messages and materials for young women about breast cancer. Insights gained from the focus groups will assist in the development and/or refinement of campaign messages and materials, as well as assist in determining best strategies for dissemination of campaign materials and messages. Discussions will be tailored to each audience segment. See Attachments B1-D3 for discussion guides and materials for testing.

CDC will not be privy to the last names, mailing addresses, telephone numbers, or email addresses of any of the focus group participants. These individuals will be recruited using the proprietary databases of a professional recruiting firm. Eligibility criteria will be established for all focus group participants, and potential participants will be screened during a telephone interview (see Attachments E–G for screening instruments). 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, unless otherwise compelled by law (see participant information sheet provided in Attachment H).

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 and, thus, there is no web content directed at children less than 13 years of age.

A2. Purpose and Use of the Information Collection

The legislative mandate of the EARLY Act directs CDC to develop an educational campaign about breast cancer that is targeted toward young women. To further CDC's efforts to fulfill that mandate, CDC created an educational campaign, entitled *Bring Your Brave,* that includes: web and social media content, videos, fact sheets, and digital media advertisements. CDC is now in the process of creating and updating *Bring Your Brave* materials to continue to reach its audience. This phase of the campaign is designed to:

1. "Increase public awareness regarding breast cancer in young women of specific ethnic and cultural backgrounds, including particular risks faced by certain ethnic and cultural groups;" and

2. "Promote educational awareness, early detection, and risk-reducing practices among young women and increase the number of young women with breast cancer warning signs who seek immediate care."

As part of the health communication process, CDC will pre-test concepts, messages, and materials with target audiences. These materials will be branded under a campaign name and logo. The purpose of this information collection is to inform development of campaign

components (concepts, messages, and materials) to assure they will motivate underserved young women, both those with average risk and those at an increased risk for developing breast cancer, to respond to calls to action and engage with the campaign. This information collection will consist of focus groups with members of the target audiences for the campaign.

One main area of inquiry will be to:

- Determining the target audiences' baseline knowledge of breast cancer in young women, the related risk to specific populations based on ethnic, racial, or family medical history factors, and actions young women can take to reduce their risk of developing breast cancer. Improved understanding in this area will allow the project team to tailor media campaign content to fill gaps in the target audiences' existing knowledge.

By conducting formative evaluation through this information collection, campaign materials can be tailored to suit the audiences' preferences and educational needs. This will improve acceptance of the campaign materials and the success of the campaign overall.

A3. Use of Improved Information Technology and Burden Reduction

Electronic data collection methods have limited applicability to focus groups, other than video- or audio-taping discussions. However, whenever possible, DCPC staff will employ electronic technology to collect and process data in order to reduce respondent burden and aid in data processing and reporting efficiency.

Efforts have been made to design discussion questions that are easily understandable, not duplicative in nature, and least burdensome. 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

Given the legislative mandate of the EARLY Act, CDC has determined that the planned data collection efforts do not duplicate any other current data collection efforts. This is the first time focus groups for Hispanic and AIAN subpopulations have been conducted, and this information collection explores new areas of inquiry for African American women.

A5. Impact on Small Businesses or Other Small Entities

There will be no impact on small businesses as a result of this data collection.

A6. Consequences of Collecting the Information Less Frequently

This is the first time focus groups for Hispanic and AIAN subpopulations have been conducted, and this information collection explores new areas of inquiry for African American women. As the health communication process illustrates, formative evaluation is a critical segment of a scientifically sound campaign effort. Formative evaluation, often encompassing concept, message, and materials testing activities, is essential in pre-testing materials to evaluate a wide

variety of dimensions that include, but are not limited to, appeal, saliency, clarity, cultural appropriateness, and readability/understandability. If a concept and/or a message is not tested, 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.

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

This information collection is being conducted using the Generic Information Collection mechanism of Focus Group Testing for Cancer Prevention and Control for DCPC, OMB No. 0920-0800. As required by 5 CFR 1320.8(d), a notice for public comments was published in the Federal Register on December 13, 2017 (Vol. 82, No. 238, pages 58606-58607; see Appendix B1). No public comments have been received.

A8.B Efforts to Consult Outside the Agency

There were no external consultations. Given the legislative nature of the EARLY Act, the proposed protocol and discussion guides were developed and reviewed extensively by DCPC staff and others directly involved in implementing the DCPC communications campaigns.

A9. Explanation of Any Payment or Gift to Respondents

Incorporating modest incentives to aid in recruitment is considered justifiable in order to boost response rates and defray the cost of participation (e.g., transportation and childcare). Also, it is standard practice among commercial market researchers to offer incentives to participants in exploratory and message- and materials-testing focus groups.

As shown by the literature referenced below, the payment of incentives can provide significant advantages to the government in terms of direct cost savings and improved data quality.

While impact of monetary compensation of focus group participation has not been empirically studied, Kruegar (1994) cautions that without providing minimal levels of monetary compensation, insufficient numbers of participants will attend and results will not be useful. However, there is substantial evidence that monetary incentives increase response rates to surveys. In a meta-analysis of 38 experiments and quasi-experiments, Church (1993) found that

nonmonetary gifts were significantly less effective than cash in generating survey response and noted that offering prepaid monetary incentives yielded an average increase of 19.1 percentage points over comparison groups.

A9.A Level of Incentive Payment

Focus group participants will be provided with a modest incentive for their participation. Participants will be given $75 for their participation in the ninety-minute groups. This incentive is based on market rates commensurate with the cities in which the data collection is to take place.

A9.B Reduced Data Collection Cost

While there is minimal published literature on focus group incentive rates, empirical evidence suggests that motivation is increased when an incentive is present. Discussion of remuneration as a technique to speed responses and expand response rates is not complete without mentioning the trade-off between the costs of incentives and the costs of efforts to foster timely and complete participation. The goal is to find the highest response rate at the lowest overall cost to the government.

In the National Adult Literacy Survey by Berlin (1992) and colleagues (OMB No. 1850-0654, exp. 8/31/1993), a $20 incentive resulted in not only higher response rates from the sample cohort but also lower costs per completed case than the comparison group. Importantly, the incentives provided higher response rates from adults with lower-than-average levels of education and basic literacy and numeracy skills (e.g., the NELS: 88 subset of high school dropouts).

A9.C Reduced Bias

The most important aspect of an incentive plan may be its potential for reducing response bias, underreporting bias, and similar sources of error. Findings from the National Survey of Family Growth (a study in which childbearing and family planning patterns are collected from young women) demonstrated that incentives not only had positive effects on response rates, but they also increased the accuracy of reporting. Incentives are necessary for testing in order to ensure that those who are willing to participate are as representative as possible of the wider public. Failure to provide a basic incentive is likely to bias samples in the direction of well-educated individuals who are generally predisposed to be helpful (http://www.cdc.gov/nchs/nsfg.htm).

A10. Assurance of Confidentiality Provided to Respondents

A10.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.

A10.B Safeguards

Respondents will be recruited by a professional recruiting firm. CDC will not create a record system for this project. Although respondent names and 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 may 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 audio-taped and transcribed, and that tapes will be destroyed after completion of each report on findings. DCPC staff, in conjunction with Hager Sharp, will collect and evaluate the audience study data. CDC will not collect information in identifiable form.

Information provided during the groups will be kept private and secure to the extent allowed by law. Participants' names or images will not be used in the final report. No statements made by participants will be linked to them by name. Only members of the focus group coordination staff will be allowed to look at the records. Participants' names or other personally identifiable information will not be shown or used in the presentation of findings.

A10.C Consent

All information provided by respondents will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Typically, informed consent will be obtained from respondents (see Attachments B1–D3, Discussion Guides) and they will be informed that participation is voluntary; 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. It has been determined that these information collection activities are not generalizable and do not qualify as human subjects research and will therefore not require IRB review and approval (Form 684).

A10.D Nature of Response

Respondent participation is entirely voluntary, as noted in the participant information sheet (Attachment H).

A11. 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 cancer 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 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 198 respondents will be involved in focus groups (22 focus groups @ 9 respondents per group). The discussion guide for each focus group can be found in Attachments B1–D3. The average burden for a focus group discussion will be ninety minutes.

Potential participants will be recruited through standard commercial recruiting practices. Similarly, potential respondents will be screened for interest and eligibility using a screening form (see Attachments E–G). Based on previous experience recruiting focus group participants from master lists of eligible or interested persons, it is estimated that twice the target number of needed respondents must be screened in order to yield the targeted number of respondents. The estimated burden per response for screening is three minutes.

The estimated burden to respondents is summarized in Table A12-A below.

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)
Hispanic Young Women	Screening Instrument	216	1	3/60	10.8
	Discussion Guide	108	1	90/60	162
African American Young Women	Screening Instrument	108	1	3/60	5.4
	Discussion Guide	54	1	90/60	81
American Indian/Alaska Native Young Women	Screening Instrument	72	1	3/60	3.6
	Discussion Guide	36	1	90/60	54
				Total	317

Information will be collected over a one-month time period. There are no costs to respondents except their time to participate in the focus groups. The total annualized burden to respondents is 317 hours.

B. Approximately 54.5% of respondents will be Hispanic women, 27.3% will be African American, and 18.2% will be American Indian/Alaska Native women. 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 (https://www.bls.gov/oes/2017/may/oes_nat.htm#29-0000) specifically originating from the Occupational Employment Statistics May 2017 National Occupational Employment and Wage Estimates, United States, Bureau of Labor Statistics. The total estimated annualized respondent cost (including the screening form) is $7,710.91.

Table A12-B: Estimated Annualized Cost to Respondents

Type of Respondents	Form Name	Number of Respondents	No. of Responses per Respondent	Total Burden (in hours)	Average Hourly Wage Rate	Total Cost
Hispanic Young Women	Screening Instrument	216	1	10.8	$24.34	$262.87
	Discussion Guide	108	1	162	$24.34	$3,943.08
African American Young Women	Screening Instrument	108	1	5.4	$24.34	$131.44
	Discussion Guide	54	1	81	$24.34	$1,971.54
American Indian/Alaska Native Young Women	Screening Instrument	72	1	3.6	$24.34	$87.62
	Discussion Guide	36	1	54	$24.34	$1,314.36
Total						$7,710.91

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 $230,029.16. This figure encompasses the salary of two GS-14 employees, communication contract costs, as well as fees for identifying and recruiting participants, incentive payments, facility rental, and transcription.

Table A14-A: Estimated Annualized Cost to the Government

Estimated Annualized Cost to the Government, per Campaign and Total	
Cost Category	Estimated Annualized Cost
Federal employee costs (adjusted for Atlanta) (10% FTE of 1 GS-14 Step 5 @ $122,718/yr) (2% FTE of 1 GS 14 Step 5 @ $122,718/yr)	$12,271.80 $2,454.36
Contractual costs for focus group facility rental, focus group moderator, participant recruitment, and report on findings, per campaign	$215,303.00
Total	**$230,029.16**

A15. Explanation for Program Changes or Adjustments

This is a new information collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

Table A16-1 presents the estimated timeline for conducting focus groups following receipt of OMB clearance.

Table A16-A: Focus Group Schedule

Activity	**Time Schedule**
Focus group recruitment	3-4 weeks after OMB approval
Focus group testing	5-9 weeks after OMB approval
Analysis of focus group results (topline reports)	10-11 weeks after OMB approval
Report writing/Recommendations to CDC based on findings	12-13 weeks after OMB approval

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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