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

Generic Information Collection

OMB No. 0920-0800

Expiration Date 10/31/2025

Supporting Statement Part A

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* The goal of this information collection is to conduct focus groups among minoritized racial, ethnic, and sexual identity groups 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 to respond to calls to action and engage with the campaign.
* Information will be collected from small, virtual focus groups. Each group will have four (4) to six (6) 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:
  + Cisgender women ages 18–44
  + Segmented into five key demographic groups: Black/African American, Hispanic, American Indian/Alaskan Native, General Population, and cisgender women of minoritized sexual identity groups (LBQA)
  + 5 groups with those who are unaware of their risk for breast cancer, or may know, but have not yet taken steps to lower or mitigate their risk.
  + 5 groups with Previvors, those who are aware of their increased risk for breast cancer and are actively taking steps to mitigate and/or manage their risk.
* 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 to Effectively Plan and Tailor Cancer Prevention and Control Communication Campaigns”). Focus groups will be held virtually across racially and ethnically diverse areas in the United States 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 to Effectively Plan and Tailor Cancer Prevention and Control Communication Campaigns, OMB No. 0920-0800. The respondent universe for this data collection aligns with that approved under OMB 0920-0800.

Approximately 9% 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 communities, while empowering them with the tools they need to fight the disease. In 2014, Congress reauthorized this legislation (Attachment 1 – 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 (BYB),* to increase knowledge of breast health and breast cancer among women, particularly among those under the age of 45. Core audience segments include women who are: i) unaware of their risk for breast cancer, or may know, but have not yet taken steps to lower or mitigate their risk; ii) aware of their increased risk for breast cancer and are actively taking steps to mitigate or manage their risk (e.g., previvors); and iii) survivors of early onset breast cancer (EOBC).

The campaign encourages these three audiences to understand their EOBC risk by focusing on five key elements:

* Encourage young women to learn about their family history of breast and ovarian cancer,
* Educate young women on the risk factors for breast cancer before age 45,
* Inspire young women to talk to their doctors if they think they may be at higher risk for breast cancer,
* Encourage young women to live a healthy lifestyle and be aware of their breast health, and
* Educate providers on the risk factors for breast cancer before age 45.

This project will build on CDC’s previous work that sheds light on the motivators, facilitators, and barriers to knowing one’s risk for EOBC. In December 2021, Team Edelman conducted a conversation analysis that revealed unique concerns among BYB’s priority groups including Black, Hispanic, American Indian/Alaska Native (AIAN), and Ashkenazi Jewish women, as well as women of LGBTQIA+ identities. In addition, Team Edelman’s peer audit revealed that messaging aimed at any audience or priority group tends to focus on one’s risk but does not focus on other important perceptions such as the benefits of knowing one’s risk, and there is little messaging aimed at previvors.

Together, these findings suggest the need to talk with BYB’s audiences and priority groups to test messages and materials, particularly because there is more to uncover about how to tailor the campaign to different segments and how women’s prevention-related behaviors have changed because of the COVID-19 pandemic. In addition, these focus groups will allow Team Edelman to better understand the information needs of previvors, an important BYB audience that were not a focus of previous formative studies. The findings will guide the refinement of BYB’s messages, materials, and dissemination strategies.

To that end, Team Edelman aims to conduct ten 90-minute, virtual focus groups with 18-44-year-old women who are i) unaware (e.g., unaware of their risk for breast cancer, or may know, but have not yet taken steps to lower or mitigate their risk) and ii) previvors (e.g., aware of their increased risk for breast cancer and are actively taking steps to mitigate and/or manage their risk). Focus groups will be further divided into five priority groups as defined in Table A1 below.

Each focus group will consist of a range of 4-6 individuals (thus, a minimum of 40 participants and a maximum of 60 participants for the overall data collection effort).

**Table A1-A. Young Women Respondents**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Young Women Respondents (ages 18-44)** | | | | | |
|  | **Black/ African American** | **Hispanic** | **General Population** | **American Indian/ Alaskan Native** | **Sexual Identity Groups (LBQA)** |
| **Unaware** | 1 group  English | 1 group  Spanish | 1 group  English | 1 group  English | 1 group  English |
| **Previvor** | 1 group  English | 1 group  Spanish | 1 group  English | 1 group  English | 1 group  English |
| **Total Groups** | 5 groups with women unaware of personal risk, age 18–44, 1 group in Spanish  5 groups with previvors, age 18–44, 1 group in Spanish | | | | |
| **Inclusion Criteria** | Include mix of   * sexual identities (e.g., Straight, Lesbian, Bisexual, Queer, and Asexual) * geographic location (i.e., urban, suburban, rural) * income levels * education levels * have/have not undergone genetic counseling and testing to better understand their risk of breast cancer. | | | | |
| **Exclusion Criteria** | Exclude women who   * are transgender * are breast cancer survivors * are employed in communication, marketing, advertising, digital media, or health fields * do not have a desktop, laptop, or smartphone for participation | | | | |

These focus groups will glean insights about a new priority group, previvors, and their information needs. In particular, these focus groups will aim to obtain insights about women’s perspectives about the following: i) knowledge and awareness of EOBC, including personal risk; ii) perceived benefits and barriers to knowing personal risk; iii) preferred channels to receive health communications; iv) resonance, authenticity, and clarity of materials; and v) likelihood to take action after viewing materials. Focus group findings will guide the refinement of BYB’s messages, materials, and dissemination strategies.

Information gathered will only be used internally to improve the BYB campaign’s materials and dissemination strategies. Information is not intended for release outside of the agency. Information gathered will not be used for the purpose of substantially informing influential policy decisions. Without these types of feedback, CDC will not have the timely information it needs to adjust its Bring Your Brave campaign and reach its primary audience.

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, virtual groups (N < 8), allow us to connect participants across the country for conversation and observation of subtle cues. Each group will have four (4) to six (6) participants and is expected to last 90 minutes. All focus groups will be led by a professional moderator selected by CDC DCPC. CDC staff will be able to observe the interviews remotely. Simultaneous translation in English will be offered for observers who attend the Spanish language focus groups. The focus groups will be digitally recorded (audio recording) and transcripts will be prepared from these recordings.

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 5A-6B 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 2A and 2B 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 Attachments 4A and 4B).

*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 younger 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, cultural, and sexual identities, including particular risks faced by certain 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 sexual identity 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 the previvor subpopulation have been conducted, and this information collection explores new areas of inquiry for underserved women, including those of minoritized sexual groups.

***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 the previvor subpopulation have been conducted, and this information collection explores new areas of inquiry for underserved women, including those of minoritized sexual groups. 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 to Effectively Plan and Tailor Cancer Prevention and Control Communication Campaigns 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. 86, No. 140, pages 40050-40051;). 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

Each participant who joins the focus group no later than 10 minutes after start time will receive a $150 electronic gift card. The incentive is a token of appreciation for 90 minutes of the participant's time and is based on market rates. The recruitment vendor partnering with Team Edelman uses an incentivization program which allows participants to choose from a number of digital gift cards, Visa digital or mailed gift card, PayPal or a check. The participant is required to show a valid ID with a current address that matches what address the participant provided during the screening process and must have verbally consented to participating in the study.

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 Edelman, will collect and evaluate the audience research 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 research 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 5A and 5B, 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.

A10.D Nature of Response

Respondent participation is entirely voluntary, as noted in the participant information sheet (Attachments 4A and 4B).

***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, sexual orientation, gender identity, 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 60 respondents will be involved in this focus group effort (i.e., 6 participants will participate in each of 10 focus groups). The discussion guide for each focus group can be found in Attachments 5A and 5B. The average burden for a focus group discussion will be ninety minutes. An additional 20 respondents will be screened (i.e., 2 potential respondents will be recruited for each of 10 focus groups) to ensure the target number of respondents is met.

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 2A and 2B). 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**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Category of Respondent** | **Form Name** | **No. of Respondents** | **Participation Time (in hours)** | **Total Burden (in hours)** |
| Individual Participants | Attachment 2A and 2B – Participant Screeners (English, Spanish) | 160 | 10/60 | 26.6 hours |
| Individual Participants | Attachment 5A and 5B – Focus Group Moderator Guides (English, Spanish) | 60 | 90/60 | 90 hours |
| **Total** |  |  |  | 116.6 hours |

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 116.6 hours.

B. 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/tables.htm#29-0000>) specifically originating from the Occupational Employment Statistics May 2022 National Occupational Employment and Wage Estimates, United States, Bureau of Labor Statistics. The total estimated annualized respondent cost (including the screening form) is $3,470.02.

**Table A12-B: Estimated Annualized Cost to Respondents**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Category of Respondent** | **Form Name** | **Number o**f **Respondents** | **No. of Responses per Respondent** | **Total Burden**  **(in hours)** | **Average Hourly Wage Rate** | **Total Cost** |
| Individual Participants | Screening Instrument | 160 | 1 | 26.6 | $29.76 | $791.62 |
| Individual Participants | Discussion Guide | 60 | 1 | 90 | $29.76 | $2,678.40 |
| Total |  |  |  |  |  | $3,470.02 |

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

None.

***A14. Annualized Cost to the Government***

The estimated annual cost to the Federal government for the proposed focus group activities is $113,200. This figure encompasses 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 | $113,200.00 |
| **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** |
| Team Edelman begins recruitment and focus groups | 2 weeks after OMB |
| Team Edelman finishes conducting focus groups | 7 weeks after OMB |
| Team Edelman submits draft report to CDC | 11 weeks after OMB |
| CDC provides comments on report | 12 weeks after OMB |
| Team Edelman submits revised report to CDC | 13 weeks after OMB |
| CDC approves report | **14 weeks after OMB** |

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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