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

A Generic Clearance Submission

Request for OMB Review

Supporting Statement Part A

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A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), Division of Cancer Prevention and Control (DCPC), requests Office of Management and Budget (OMB) approval of a generic clearance to conduct audience research to effectively plan new and/or tailor existing cancer communication campaigns. 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). A copy of the legislation is included in Appendix A1—Legislative Authority.

According to the report entitled *United States Cancer Statistics (USCS) 2004 Incidence and Mortality*, 1,342,126 people were diagnosed with cancer during 2004 while 553,880 died of the disease. Furthermore, it is estimated that 10.8 million American are living with cancer (Reis, 2007).

Among cancers affecting both men and women, colorectal cancer is the nation's second leading cause of cancer deaths. In 2004, 145,083 new cases of colorectal cancer were diagnosed and 53,580 adults died from this disease in the United States (USCS). There is strong scientific evidence that colorectal cancer screening helps prevent the disease, by finding precancerous polyps that can be removed before they turn into cancer. Screening also helps find this cancer early, when treatment works best. However, only 61% of Americans have been screened according to national guidelines. (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5710a2.htm). Thus, activities to promote screening for colorectal cancer are a high priority for DCPC as illustrated by one of the Division's programs *Screen for Life: National Colorectal Cancer Action Campaign*.

The prevention and control of gynecologic cancers is another major area of emphasis with DCPC. More than 73,000 women in the United States were diagnosed with a cancer affecting the reproductive organs in 2004. In the same reportable year, over 27,000 women in the United States died of some form of gynecologic cancer—with ovarian cancer representing the majority of mortalities (USCS, 2004). In response, DCPC plans to continue awareness activities as specifically authorized by the Gynecologic Cancer Education and Awareness Act of 2005, Section 247b-17 of the PHSA, also known as Johanna's Law (Appendix A2). This legislation was unanimously passed by the U.S. House and Senate (109th Congress) in December of 2006, and signed into law by President George W. Bush on January 12, 2007. 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*. The fiscal year 2008 Senate Appropriations Language Full Committee Report states, "The Committee is encouraged by the progress that has been made by CDC, in coordination with the Office of Women's Health to initiate a national education campaign on Gynecologic Cancers. The Committee strongly urges the rapid completion of the evaluation of past and present activities to increase the awareness and knowledge regarding gynecologic

cancers and the creation of a strategy for improving efforts to increase awareness and knowledge of the public and health care providers with respect to gynecological cancers."

The Health Communication Process

In an effort to fulfill its mission, DCPC supports the scientific development, implementation, and evaluation of various health communication campaigns, with a focus on specific cancer burdens. DCPC efforts are rooted in the Health Communication Process, a scientific model developed by the U.S. Department of Health and Human Services' National Cancer Institute to guide sound campaign development. The Health Communication Process framework consists of four stages: 1) planning and strategy development, 2) developing and pretesting concepts, messages, and materials, 3) implementing the program, and 4) assessing effectiveness and making refinements (National Cancer Institute, 2002). The phases of program development are circular in nature such that there is an ongoing loop of planning, implementation, and refining to retain scientific accuracy, reflect current audience knowledge and needs, and, ultimately, maximize overall effectiveness of the effort.

One critical facet of the health communication process model is its ability to illustrate the evaluation spectrum beginning with formative evaluation (stage 2), process evaluation (stage 3), and extending to outcome or summative evaluation (stage 4) (Cooper et. al, 2005). Formative evaluation often is conducted during program development to glean valuable information on the problem as well as the knowledge, attitudes, and beliefs of the target audience(s). Process evaluation assesses previously implemented program tactics often through quantifiable means; outcome evaluation measures overall population change that may or may not have occurred as a result of an organized effort. Strategic participation in all stages of the evaluation spectrum will increase the likelihood of achieving the goals and/or objectives of a health communication campaign.

Focus groups to be conducted under the auspices of this generic OMB clearance will assess numerous qualitative dimensions that include, but are not limited to knowledge, attitudes, beliefs, behavioral intentions, information needs and sources, and compliance with recommended screening intervals. Insights gained from the focus groups will assist in the development and/or refinement of campaign messages and materials.

Initial data collection efforts will relate to time-sensitive DCPC activities focusing on colorectal and gynecologic cancers. As cancer burdens evolve and public compliance with recommended screening practices shifts, it is likely that DCPC will be engaged in forthcoming communication campaign efforts beyond its existing commitments related to colorectal and gynecologic cancers. Therefore, as the health communication process model dictates, the need to collect information from the public will also increase. Accordingly, it is not unlikely that these efforts will be mandated by Congress with aggressive deadlines, as is the case with the *Inside Knowledge: Get the Facts About Gynecologic Cancer* campaign. Thus, campaign planners must be able to conduct formative audience research in a very timely manner. This request for a generic clearance fills this gap.

A2. Purpose and Use of the Information Collection

The purpose of this generic clearance request is to conduct formative evaluation activities, inclusive of message, concept, and/or materials testing, for health communication campaigns in the area of cancer prevention and control. Using a reference set of OMB-approved qualitative items (Appendix E), tailored information collection instruments will be designed to meet campaign-specific, population-specific, or context-specific needs. The information collected will be used by DCPC staff to appropriately plan for the launch of a new campaign, tailor existing campaign efforts, and/or develop forthcoming campaign materials in an iterative manner consistent with the Health Communication Process.

Both *Screen for Life* and *Inside Knowledge* have immediate audience research needs with respect to message, concept and materials testing. While these are two very distinct initiatives in different stages of maturity and brand development, both campaigns require focus group testing with consumers and health care professionals so that limited resources can be used to direct campaign efforts in the most efficient and audience-appropriate manner. The *Screen for Life* and *Inside Knowledge* initiatives are described in more detail below.

Screen for Life: National Colorectal Cancer Action Campaign

Screen for Life: *National Colorectal Cancer Action Campaign* is a multimedia awareness campaign created in1999 by CDC in partnership with the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services) and the National Cancer Institute. In an effort to educate Americans about colorectal cancer and the benefits of screening, the campaign targets men and women aged 50 and older as well as health care providers. Specific populations, such as African Americans and those individuals whose native language is Spanish, are also embedded in the target audience segment.

Basic campaign messages are the following:

- Among cancers affecting both men and women, colorectal cancer is the second leading cancer killer in the United States.
- Medicare and most insurance plans help pay for colorectal cancer screening.
- Don't wait for symptoms. Polyps and/or cancer in the colon or rectum do not always cause symptoms—that's why it is important to be screened for colorectal cancer.
- Screening saves lives.
- Screening helps prevent colorectal cancer. Screening tests help find precancerous polyps so they can be removed before they turn into cancer.
- Screening helps find colorectal cancer early, when treatment can be very effective.
- Risk increases with age, and most colorectal cancers occur in people aged 50 and older.
- If you 50 or older, see your doctor and get screened regularly for colorectal cancer.

Campaign materials include television and radio public service announcements (PSAs) in English and Spanish, print advertisements, posters, fact sheets and brochures for patients in English and Spanish, a fact sheet for health care providers, airport dioramas, newspaper articles, and video and audio news releases in English and Spanish. In 2004-2005, the campaign began a partnership with the National Colorectal Cancer Research Alliance (NCCRA) and cofounder

Katie Couric, and with the Entertainment Industry Foundation (EIF), to produce print and broadcast PSAs and other materials, including new print materials featuring Ms. Couric and broadcast PSAs featuring actors Morgan Freeman, Diane Keaton, and Jimmy Smits.

Screen for Life's website (www.cdc.gov/screenforlife) includes campaign background information, information about colorectal cancer, scientific resources, and campaign materials that can be downloaded and/or ordered for use in communities, medical practices, and other settings. The website also serves as a resource for health educators, health care providers, state and local organizations, and others interested in colorectal cancer. All 50 state health departments, two tribal organizations and the District of Columbia are active partners in the campaign effort. CDC supports states' educational efforts by designing materials that are easy to localize, download and print; and by offering free local tagging for broadcast PSAs.

Screen for Life PSAs are distributed nationally to a broad range of television, radio and print media outlets. The television PSAs are distributed to approximately 1,000 TV stations in all 210 U.S. media markets, as well as to national networks and national and regional cable systems. Radio PSAs are distributed to approximately 1,200 radio stations that appeal to adults age 50 and older, African Americans, and/or Hispanics. Print PSAs are sent to approximately 2,000 magazines and 5,500 daily and weekly newspapers. Print and broadcast materials are also sent to State Health Departments and are available on the campaign website. Appropriate tracking mechanisms are in place to measure and monitor viewer/listener impressions and other significant data related to TV, radio, print and other media. Since the campaign's launch in 1999 – February 2008, SFL PSAs have garnered more than 5.2 billion audience impressions, the number of times the PSAs have been seen or heard, worth more than $66 million in donated media placements.

Campaign priorities include developing new print and broadcast PSAs, as well as materials specifically for use by health care providers. These activities require focus group research to ensure the campaign products are developed with audience accuracy, appeal, and overall need. The proposed generic clearance is a critical element of DCPC's overall plan to meet this need.

Inside Knowledge: Get the Facts About Gynecologic Cancer

CDC is developing campaign materials, as mandated by Congress, to provide information about the major gynecologic cancers (cervical, ovarian, vulvar, uterine, and vaginal) and to convey the message that many cancers have warning signs and symptoms and are curable if detected early and treated appropriately. In addition, campaign materials will educate women and health care providers about available screening tests, risk factors and prevention strategies.

The primary audiences for this initiative consist of women of all races and ethnicities and health care providers. CDC campaign activities include the following:

- Design of a campaign identity/logo that provides the opportunity for tailoring/adaptation for each of the individual gynecologic cancers.
- Design and creation of a gynecologic cancer homepage and expanded website within CDC's Division of Cancer Prevention and Control's website.

- Creation and dissemination of consumer/patient fact sheets on ovarian, cervical, uterine, and vaginal/vulvar cancers to be posted on CDC's DCPC website and to be made available to order through CDC's distribution center.
- Adaptation/translation of consumer/patient fact sheets into Spanish.
- A comprehensive brochure that presents gynecologic cancers as a whole.
- Creation, production, and distribution of a range of new materials including posters, print and broadcast public service announcements, and dioramas for use in airports, malls, and other transit and high trafficked stations.
- Development of resources for health care providers—such as a gynecologic cancers slide set—a downloadable educational tool.

Campaign priorities include developing new print and broadcast PSAs, as well as materials specifically for use by health care providers. These activities require focus group research to ensure the campaign products are developed with audience accuracy, appeal, and overall need. The proposed generic clearance is a critical element of DCPC's overall plan to meet this need.

The *Screen for Life* and *Inside Knowledge* campaigns are key DCPC activities with urgent needs for information. The tools and experience to be gained through audience research in these areas can be applied to other cancer prevention and control campaigns over the three years of the proposed generic clearance. The ability to tailor information collections to specific circumstances, and the ability to move rapidly from one phase of the Health Communication Process to another, are major advantages of the generic clearance format. In some cases, preliminary cancer control messages may already exist, and DCPC could begin focus group testing at a point corresponding to a later stage of the Health Communication Process. The proposed generic clearance will provide DCPC with the flexibility to conduct tailored information collections involving multiple campaigns on an as-needed basis.

A3. Use of Improved Information Technology and Burden Reduction

Electronic data collection methods have limited applicability to focus groups, other than 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 items 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

Based on a division-wide review, CDC has determined that the planned data collection efforts do not duplicate any other current or previous data collection efforts.

A5. Impact on Small Businesses or Other Small Entities

As is the case with *Screen for Life* and *Inside Knowledge*, many communication campaigns incorporate health care providers into the target population. When formative, materials-testing, and/or outcome research is a necessity with this audience, CDC works through established medical and professional societies and research contractors to gain access and obtain necessary participation. Research efforts will be carefully planned to minimize the burden on physician practices and other small entities.

A6. Consequences of Collecting the Information Less Frequently

As the health communication process illustrates, formative evaluation is a critical segment of a scientifically sound campaign effort. Formative evaluation, 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

A notice for public comments on the proposed data collection activities required by 5 CFR 1320.8(d) was published in the Federal Register on January 29, 2008 (Vol. 73, No. 19, page 5197). CDC has received no comments in response to this notice. A copy of the notice is included in Attachment B—60-Day Federal Register Notice.

A8.b Consultation

The following individuals inside the agency have been consulted on the design of the generic clearance package including audience research questionnaire development:

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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 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.

Level of Incentive Payment

Under the terms of the subject OMB package, focus group participants will be provided with a modest cash incentive for their participation. Consumers will typically be compensated $100 upon completion of the 120 minute focus groups while health care providers will typically be

remunerated $200 for their participation. These compensation levels were recommended by independent consultants and senior analysts employed by qualitative research firms.

Reduced Data Collection Cost

While there is minimal published literature on focus group incentive rates, empirical evidence suggests that 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, 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).

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

The CDC Privacy Act Officer has reviewed this OMB submission and determined that the Privacy Act is not applicable. Respondents will be recruited by the data collection contractor, Ogilvy Public Relations Worldwide, using established record systems such as proprietary databases of professional organizations (e.g., the American Medical Association), commercial focus group companies, and other sources. 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. Nor will this information be made available to CDC. Upon completion of the focus group, the organization responsible for recruitment will immediately shred all participant information collected. 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.

Respondents will be informed that focus groups will be audio-taped and transcribed, and that audio-tapes will be destroyed after completion of each report on findings. DCPC staff, in conjunction with a communications contractor, will collect and evaluate the audience research data.

All information provided by respondents will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Informed consent will be obtained from respondents (see Attachment D) and they will be informed prior to participation that their responses will be treated in a secure manner. The proposed activities do not require IRB review and approval. If a specific information collection to be conducted under the generic clearance is determined to require IRB approval, DCPC will obtain the required approval.

A11. Justification for Sensitive Questions

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

A12. Estimates of Annualized Burden Hours and Costs

A. The Division of Cancer Prevention and Control estimates that 864 respondents will be involved in focus groups each year (72 focus groups @ 12 respondents per group). The discussion guide for each focus group will consist of questions drawn from a pre-approved reference set (see Attachment E) that will be customized according to the applicable type of cancer, target population, and phase of the health communications development process. The average burden for a focus group discussion will be two hours.

Similarly, potential respondents will be screened for interest and eligibility using a customizable Screening Form, also compiled from a list of pre-approved questions (see Attachment D). Based on 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 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)
General Public	Screening Form	1,382	1	3/60	69
	Focus Group Guide	691	1	2	1,382
Health Care Providers	Screening Form	346	1	3/60	17
	Focus Group Guide	173	1	2	346
				Total	1,814

Information will be collected over a three year time period. There are no costs to respondents except their time to participate in the focus groups. The total annualized burden to respondents is 1,814 hours.

B. Approximately 80% of respondents will be members of the general public and 20% of respondents will be health care professionals. 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 website (http://www.bls.gov/ncs/ncswage.htm#Wage_Tables) specifically originating from the June 2006 National Compensation Survey. The total estimated annualized respondent cost (including the screening form) is $52,843.

Table A12-B: Estimated Annualized Cost to Respondents

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)	Average Hourly Wage Rate	Total Cost
General Public	Screening Form	1,382	1	3/60	69	$19.76	$1,363
	Focus Group Guide	691	1	2	1,382	$19.76	$27,308
Health Care Providers	Screening Form	346	1	3/60	17	$66.59	$1,132
	Focus Group Guide	173	1	2	346	$66.59	$23,040
						Total	$52,843

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 $500,000 ($250,000 per campaign). This figure encompasses the salary of two GS-13 employees, communication contract costs, as well as fees for identifying and recruiting participants, incentive payments, facility rental, and transcription.

Estimated Annualized Cost to the Government, per Campaign and Total	
Cost Category	Estimated Annualized Cost
Federal employee costs, per campaign (50% FTE of 1 GS-13 @ $90,000/yr)	$45,000
Contractual costs for focus group facility rental, focus group moderator, participant recruitment, and report on findings, per campaign	$205,000
Subtotal, per Campaign	**$250,000**
Total, average of 2 Campaigns per year	**$500,000**

A15. Explanation for Program Changes or Adjustments

This is a new information collection.

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. A three year generic clearance is requested.

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

Activity	Time Schedule
Focus group recruitment	1-2 weeks after OMB approval
Focus group testing	3-4 weeks after OMB approval
Analysis of focus group results (topline reports)	6 weeks after OMB approval
Report Writing/Recommendations to CDC based on Findings	2.5 months after OMB approval

Focus group findings will namely inform initial campaign planning efforts, refresh existing materials, and/or 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

Not applicable.

A18. Exemptions to Certification for Paperwork Reduction Act Submissions

Not applicable. No certification exemption is being sought.

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