DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date:
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To: Office of Management and Budget (OMB)

Through: Mary Forbes, Report Clearance Officer, DHHS
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From: Nina Goodman, Acting Associate Director, Project Officer
Office of Communications and Education (OCE)
National Cancer Institute/NIH

Subject: Generic Sub-study, **NCI Message Testing with the General Population** under "Formative Research, Pretesting, and Customer Satisfaction of NCI's Office of Communications and Education," (OMB No. 0925-0046-18, Expiration Date 2/28/13)

The information collection request described in this memo supports the Office of Communications and Education (OCE) at the National Cancer Institute (NCI).

The OCE submits for OMB review the proposed NCI research project, "NCI Message Testing with the General Population." As a world leader in cancer research, NCI's Web site (www.cancer.gov) and communication products are a primary means of communication and education for its major audiences. The research objectives guiding this sub-study are to explore and indentify ways in which the changes in cancer research and the critical role that NCI plays in moving cancer research forward can be most clearly communicated and disseminated to the general population.

Background on Project

Recognizing that cancer research and treatment have become increasingly complex, NCI is invested in ensuring that information about the changes in cancer research, the approaches taken to cancer treatment, and the critical role that NCI plays in addressing cancer treatment and prevention as well as moving cancer research forward is clearly communicated and disseminated to its major audiences, including the general population. To this end, the Communications Planning and Coordination Branch (CPCB) within NCI/OCE has developed, to date, themes and content that it sees as important to communicate about NCI and the research efforts underway to prevent and treat cancer. Three central themes have currently been proposed, each with their own sub-themes and proposed content/storylines **(see Attachment 18A for details).** The three central themes include:

- **Theme 1:** Our understanding of cancer biology has radically changed how we conceptualize both prevention and therapeutic options for controlling cancer.
- **Theme 2:** We have new tools and vast computing power that enable us to find answers at a molecular level, with the potential for much more rapid advances in both science and care. Our understanding of cancer at the molecular level will allow doctors to tailor appropriate cancer treatments to individual patients.
- **Theme 3**: At the end of the same decade that has brought the advent of much accelerated scientific discovery and improved cancer care and treatment, the NCI budget has essentially the same buying power as it did at the start of the decade, insufficient to fully realize the potential we see to reduce the Nation's cancer burden.

The OCE is interested in conducting thematic and content testing of these themes through a focus group study. The focus groups will be comprised of members of the general public using some variation of the proposed themes and messages. The results from this research will help inform NCIs immediate and future communications efforts.

Background Information on Focus Groups

Focus groups, or group interviews, are used to obtain insights into target audience perceptions, beliefs, and attitudes in the early stages of the communication process (i.e., in concept, strategy and materials development).[1] Focus groups are usually composed of 8 - 9 people who have characteristics similar to the target audience or subgroups of the target audience. The groups are conducted by a professional moderator who keeps the session on track while allowing respondents to talk openly and spontaneously. The moderator uses a loosely structured discussion outline, which allows him/her to change direction as the discussion unfolds and new topics emerge. Focus groups are valuable in exploring consumer reactions to design and message concepts before additional resources are put into their development.

Proposed Research: Focus Groups with the General Population

NCI proposes conducting 6 focus groups in two distinct locations in the United States. Focus group participants will include members of the general public who constitute advocates, change agents, and potential opinion leaders in health and cancer. To include a variety of perspectives, the participants in two of the groups will be unofficial advocates associated with cancer causes. Two of the groups will include individuals who are civically engaged and active in health issues including cancer and as such represent potential change agents and the participants in two of the groups will be actively engaged on-line concerning issues of health. Each of these groups, as defined for the purposes of this study, is described in more detail below:

- *Unofficial advocates:* These are individuals who are actively engaged, albeit not professionally, in fund raising, awareness raising, and even education activities in support of cancer prevention and treatment.
- *Civically engaged and active individuals (potential change agents):* These people will have done things such as signed a petition, attended a public meeting, written a letter to a media outlet or public official, or served as an official of a civic group related to health issues, including cancer.
- *Actively engaged on-line concerning health issues:* These individuals will write, actively engage with or consistently read blogs, chats, twitter feeds, or on-line health sites and conversations to keep abreast of or influence health issues, including cancer.

An accurate knowledge of who NCI is will also be required of a portion of the participants in each group. Additionally, the focus group participants will include a diverse mix of adults aged 25 to 65 and of men and women. They will also include a mix of those with and without a college education as well as a mix of race/ethnicity.

Three focus groups will be conducted in Chicago, IL and 3 others will be conducted in another location yet to be determined. Focus groups will not be conducted in the immediate Washington, DC metropolitan area so as to avoid recruiting participants who have attenuated knowledge about federal government entities (as is often the case among residents in the nation's capital region).

[1] Krueger, R.A., (1994). Focus groups: A practical guide for applied research, (2nd ed.) Thousand Oaks, CA: Sage Publications.

The detailed focus group design is presented below:

Focus Group Research Design

Type of Participants	Location #1: Chicago, IL	Location #2: TBD	Total
Unofficial advocates	1 focus group (9 participants)	1 focus group (9 participants)	2 focus groups (18 participants)
Civically engaged and active potential change agents	1 focus group (9 participants)	1 focus group (9 participants)	2 focus groups (18 participants)
Actively engaged on-line	1 focus group (9 participants)	1 focus group (9 participants)	2 focus groups (18 participants)
Total	**3 focus groups (27 participants)***	**3 focus groups (27 participants)**	**6 focus groups (54 participants)**

NCI will use a contractor, FHI 360 (formerly AED), to conduct data collection activities. Focus groups discussions will be conducted by an experienced moderator. Each focus group discussion will last approximately 90 minutes. A moderator's guide **(Attachment 18B)** will be used to ensure that the focus groups stay on-track. The guide will be organized around the following main topic areas:

- Perceptions of NCI
- Most important themes and sub-themes
- Usefulness of themes and sub-themes for each audience
- Use and appeal of story-lines
- Dissemination and placement of messages
- Thoughts on NCI awareness raising
- Reactions to NCI clinical trial awareness raising ideas

FHI 360 will work with an experienced recruitment agency to recruit and schedule the participants for the focus groups. Recruiters will use a screener **(Attachment 18C)** to screen focus group participant prior to scheduling their participation in order to ensure that they meet the eligibility criteria. The screening questionnaire has been carefully thought out so that the questioning process is short, easy to-understand, friendly, and efficient. Ten participants will be recruited for each focus group to ensure that 8 to 10 show up for the groups. The focus groups will be held at a convenient time of day for working people – e.g., at noon or in the late afternoon and evening.

All respondents will receive modest remuneration of $75. This remuneration will provide participants with compensation in order to defray the cost of participation (which includes approximately 2 hours of their time: going through the screening procedures, providing consent, and participating in the focus group). Research on participation in qualitative research indicates that, without providing minimal levels of incentive, insufficient numbers of participants will attend and costs associated with additional recruitment efforts may need to be incurred. In a previous Generic Sub-Study, "NCI Cancer.gov Evolution - User Focus Groups and Triads" (OMB No. 0925-0046-02, Expiration Date 2/28/13), FHI 360 reached out to professional recruitment firms to provide practical insight into the amount of remuneration qualitative research participation. Estimates ranged from $75 to $100 for a two-hour research commitment.

Analysis of the focus group data will employ a notes-based approach that relies primarily on observation notes, debriefing session notes, and summary comments made after the conclusion of each focus group. All of these sources will be used to identify and explore key findings and emerging themes. The research questions will be used as a framework for organizing data. The conduced analysis will permit the reporting of themes and issues across and between data from the three respondent groups. The analysis will be presented in a report to NCI.

All data will be collected by the contractor, FHI 360, and all personal identifiers will be excluded from the data records. Participation will be strictly voluntary and based on informed consent **(Attachment 18D for consent form)**. Prior to participating in the group discussion, respondents will be asked to read and sign a consent form. Individual respondents will not be identified. The data each participant provides will be grouped with the data from others for the purpose of reporting and presentation. Participant names will not be used. Any necessary identifying or

potentially identifying information (e.g., signed consent agreements) will be secured and kept separate from the data records. The group proceedings will be audiotaped, but participants' faces will not be video-taped. The voice recordings will only be listened to by the research team to aid with report writing. The recordings will be kept in a secured location and will be destroyed by December 31, 2015.

All information provided by respondents will be kept secure to the extent permitted by law. FHI 360 will do the analysis of the data and write the report of the findings. Findings in the report delivered to NCI will be reported in the aggregate and no identifiable individual responses will be provided. NCI's Office of Human Subjects Research (OHSR) and FHI 360's Institutional Review Board (IRB) Research Integrity Officers will review the research instruments and ensure that all necessary human subject protection procedures are in place.

The NIH Privacy Act Officer has been contacted to confirm that the information collected will be covered under the Privacy Act.

To prevent the misinterpretation of the data, particularly the perception that the results are generalizable, NCI will take steps to ensure that the research findings are not taken out of context, misrepresented, or misused. NCI will include the purpose and formative nature of the sub-study, as well as the qualitative research methodology along with its limitations, in any presentation of data and results generated from this sub-study.

Participant Burden

There will be a maximum of 60 participants. An average total participation time will be 2 hours; this include 110 minutes for the check in/out procedures of the focus group and focus group discussion and 10 minutes for the recruitment/screening time, 10 minutes for consent procedures and 10 minutes for check-in and check-out procedures the day of the focus group. This culminates in a maximum total hour burden of approximately 123 hours.

Estimates of Hour Burden					
Types of Respondents	**Instrument**	**Number of Respondents**	**Frequency of Response**	**Average Response Time (Hours)**	**Total Annual Hour Burden**
General public	Screener (**Attachment 18C**)	75	1	10/60 (0.167)	**13**
	Moderator Discussion (**Attachment 18B**)	60	1	110/60 (1.8)	**110**
Total		135		2.0	**123**

The full generic study, approved on February 10, 2010, requested a total of 7,050 burden hours. There have been 16 previous sub-studies approved by OMB under this umbrella submission, totaling 2520 burden hours requested to date. Approval by OMB of this sub-study would bring the total burden hour requested to date for 0925-0046 to approximately 2643. This leaves 4,407 burden hours for approval of additional sub-studies.

Thank you for your consideration of this proposed sub-study 0925-0046-18. Please feel free to contact me if you have any questions. Nina Goodman, Acting Associate Director, Office of Market Research and Evaluation, Office of Communications, National Cancer Institute; Telephone: 301-435-7789; Email: goodmann@mail.nih.gov

Attachments (below):

18A) NCI Messages' Themes, Sub-Themes and Proposed Content
18D) Consent form

Attachments (separate file):

18B) Moderator's guide
18C) Recruitment screener

Attachment 18A: NCI Message Matrix
(Themes, Sub-Themes and Proposed Content)

Central Theme	Sub-Themes	Proposed Storylines
THEME 1: Our understanding of cancer biology has radically changed how we conceptualize both prevention and therapeutic options for controlling cancer.	***Sub-theme 1A***: Controlling cancer is not a magic-bullet scenario.	Storyline 1A1: Cancer is not a single disease, but a complex set of diseases that display some common characteristics (and biological processes).
		Storyline 1A2: Cancers can be controlled in many different ways: Prevention, screening for early-stage cancers, more precise diagnostic tests, and better therapies are all essential strategies.
		Storyline 1A3: Advances against cancer depend on science of many kinds: Molecular and cell biology, genetics, virology, immunology, chemistry, population sciences, human behavior, and many other avenues of research.
	Sub-theme 1B: Advances in early diagnosis and better treatments over the past decade have led to substantial advances in controlling cancer.	Storyline 1B1: Recent NCI-funded study shows that women with early-stage breast cancer can now safely undergo less invasive, lymph-node sparing surgery, which reduces often painful long- term side effects including swelling and numbness.
		Storyline 1B2: The National Lung Screening Trial (NLST) found that 20 percent fewer lung cancer deaths occurred among current and former heavy smokers who were screened with low-dose spiral CT compared to chest X-ray due to more accurate early detection.
		Storyline 1B3: In neuroblastoma, a cancer found mostly in children, the addition of immunotherapy to standard therapy was found to greatly increase the percentage of patients with “high-risk” disease (most difficult to cure and most likely to relapse) who were alive and free of disease progression after two years.
		Storyline 1B4: From 1975 through 2000, deaths from colorectal cancer declined by 26 percent in the U.S., due to changes in risk factors, increased screening, and advances in treatment. More than 50 percent of this decline can be attributed to screening tests that identify early-stage cancers and adenomatous polyps, which can be precursors to colorectal cancer, for removal.
	Sub-theme 1C: Improvements in care and treatment have improved the quality of life for most people living with cancer	Storyline 1C1: Use of new antiemetic drugs (which prevent nausea and vomiting) and chemotherapy I.V. ports have made treatment much easier for patients.

Central Theme	Sub-Themes	Proposed Storylines
THEME 2: We have new tools and vast computing power that enable us to find answers at a molecular level, with the potential for much more rapid advances in both science and care. Our understanding of cancer at the molecular level will allow doctors to tailor appropriate cancer treatments to individual patients.	***Sub-theme 2A***: Cancer treatment for many cancers will involve targeted therapies and molecularly informed cancer care.	Storyline 2A1: The Therapeutically Applicable Research to Generate Effective Treatments (TARGET) Initiative project team focusing on Acute Lymphoblastic Leukemia (ALL), is studying patients with early relapse in order to identify new genomic changes that are associated with treatment failure and to identify novel therapeutic targets.
		Storyline 2A2: The Cancer Genome Atlas (TCGA) has a goal of identifying the genomic changes in more than 20 types of human cancer over the next several years. With support from NCI and NHGRI, a robust collaborative network of institutions and investigators has been established to accrue and process specimens and generate comprehensive, multi-dimensional genomic data made rapidly available to the research community.
		Storyline 2A4: Brain cancer: Analysis of data from The Cancer Genome Atlas (TCGA) revealed that glioblastoma multiforme, the most aggressive form of brain cancer, is not a single disease but has at least four molecular subtypes. This finding is paving the way for more informed selection of therapies for these patients.
		Storyline 2A5: Lung cancer: Crizotinib, a drug that targets cancer-causing chromosomal rearrangements involving the gene *ALK* in patients with non-small cell lung cancer, was made possible through molecular tumor characterization that was conducted at NCI-designated cancer centers. More than half of patients in a clinical trial of Crizotinib had partial or complete shrinkage of their tumors.
		Storyline 2A6: Melanoma: In a phase 1 study of the drug PLX4032, designed to target a common genetic change in melanoma tumors, the vast majority of patients responded to treatment. Eighty-one percent of patients in the trial who received the recommended phase 2 dose of the drug had a partial or complete response.
	Sub-theme 2B: The future of cancer care is not "a cure" or "the cure" but many treatment modalilties with many different goals.	Storyline 2B1: Cancer is an enormously complex disease and a single cure or treatment is simply not possible for the vast majority of cancers.
		Storyline 2B2: The future we envision now for most cancers is for management by prevention before it occurs and as a chronic disease after it is diagnosed.

Central Theme	Sub-Themes	Proposed Storylines
THEME 3: At the end of the same decade that has brought the advent of much accelerated scientific discovery and improved cancer care and treatment, the NCI budget has essentially the same buying power as it did at the start of the decade, insufficient to fully realize the potential we see to reduce the Nation's cancer burden.	***Sub-theme 3A***: Our emerging understanding of cancer biology and cancer treatment has important ramifications for decision leaders, policy makers, and the public.	Storyline 3A1: Public understanding of cancer research is based on perceptions formed 30 years ago.
		Storyline 3A2: The national conversation about cancer needs to reflect sustained and accelerated support in order to realize the potential advances science is poised to make against cancer.
	Sub-theme 3B: Progress against cancer requires sustained investment on a national level.	Storyline 3B1: Cancer presents a scientific problem of such complexity that a national strategy and national investment are essential to achieving progress.
		Storyline 3B2: In this new phase of cancer research, the National Cancer Institute's role as manager of the nation's investment in cancer research is more important than ever to identify research priorities and leverage the efforts of the private, academic and government sectors.
		Storyline 3B3: Individual investigator grants remain a fundamental tool for knowledge growth and progress against cancer. Research teams and multi-institutional efforts are, however, an increasingly important part of the research portfolio.
		Storyline 3B4: The health of NCI is tied to the health of NIH. NIH funding, which has been flat for nearly a decade, has not kept pace with inflation.
	Sub-theme 3C: Dollars invested in the cancer research portfolio yield dividends both in preventing and controlling cancer and in economic benefits to the Nation.	Storyline 3C1: The U.S. leads the world in biomedical research. It is a leading source of intellectual property, new products and technologies, new companies, and high-skill jobs.
		Storyline 3C2: Controlling cancer is essential to managing the nation's long-term health care costs.

Attachment 18D: Informed Consent Form

Identification of Project	**NCI Message Testing with the General Population**
Statement of Age of Subject	I state that I am at least 18 years of age, in good physical health, and wish to participate in research being conducted by the Office of Market Research and Evaluation of the National Cancer Institute, Rockville, MD 20852.
Purpose	The purpose of this research is to explore the specific ways in which NCI can provide more comprehensive and current cancer-related information about their mission and goals. NCI wants to make certain that the changes in cancer research and the critical role that NCI plays in moving cancer research forward is clearly communicated and disseminated.
Procedures	Participants will be asked to join a focus group at which point they will be asked a series of questions about their perceptions, beliefs, and attitudes towards themes and content that NCI sees as important to communicate about NCI, cancer, and the research efforts underway to prevent and treat cancer. The total time involved in the focus group, including instructions, will be no more than 90 minutes.
Confidentiality	All information collected in this study will be kept secure to the extent permitted by law. I understand that the data I provide will be grouped with data others provide for the purpose of reporting and presentation and that my name will not be used. I understand that the focus group will be audiotaped, but my face will not be video-taped. The voice recording will not be played to others besides the research team without my written permission. The recordings will be kept secured location and will be destroyed by December 31, 2015.
Risks	I understand that the risks of my participation are expected to be minimal in nature.
Benefits, Freedom to Withdraw, & Ability to Ask Questions	I understand that this study is not designed to help me personally. Rather, investigators hope to gain feedback on themes and messages around prevention and treatment of cancer. I am free to ask questions or withdraw from participation at any time and without penalty.
Contact Information of Investigators	Name: Meredith Grady Senior Program Officer**;** Office of Communications and Education Telephone: 301-435-5646 Email: gradym@mail.nih.gov

Printed Name of Research Participant _____

Signature of Research Participant _____

Date_____