DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

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To: Office of Management and Budget (OMB)

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From: Nina Goodman, Project Officer
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Subject: **Bundled Generic Sub-studies under "Formative Research, Pretesting, and Customer Satisfaction of NCI's Office of Communications and Education", OMB No. 0925-0046, Expiry Date 02/28/2013.**

Sub-Study, "Testing of Messages for an NIH Clinical Trial Public Awareness Campaign," Proposed OMB No. 0925-0046-**05**

The National Cancer Institute's Office of Communications and Education (OCE) submits for OMB the proposed NCI research sub-study, "Testing of Messages for NIH Clinical Trial Public Awareness Campaign." NCI proposes working with other NIH Institutes to develop a public awareness campaign around clinical trials. The goal of the campaign is to show the benefits of clinical trials and the importance of NIH-supported clinical research for the public's health, and highlight the need for clinical trial participants.

Background on Project

The challenge of recruiting research participants has serious implications for the success or failure of research. NIH data indicate that 85 percent of trials do not finish on time due to low patient participation and 30 percent of trial sites fail to enroll even a single patient[1]. One of the major barriers to recruitment of participants is their lack of awareness about clinical trials. Forty percent of adults report that they do not understand the nature of clinical trials or how they are performed[2]. Similarly, in a study of 1,013 U.S. adults, only 34 percent of respondents had heard of clinical trials. In a recent Research!America national public opinion survey just 15 percent of respondents said that they or anyone in their families had ever participated in clinical research[3].

1 http://depts.washington.edu/ccph/PM_112009.html
2 National Survey, 2006; Charlton Research Company for Research! America; http://www.researchamerica.org/uploads/poll. clinicalresearch.pdf

In an effort to increase public awareness about clinical trials, particularly treatment trials, the National Cancer Institute's Office of Market Research and Evaluation (OMRE) will conduct message testing research to inform the campaign planning. This research will build upon these previous surveys conducted almost ten years ago to develop messages to reach the campaign goals. The objectives of this research task is to explore differences in target audiences' attitudes toward and understanding of treatment clinical trials; test messages about clinical trial participation to assess comprehension, relevance, benefits, and credibility; explore differences in target audiences' reactions to the messages; confirm that there are no negative interpretations or reactions to the messages; and assess audiences' preferred channels. This request includes as attachments the screener, consent form and moderator guide to conduct this research task.

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).[4] Focus groups are usually composed of 8–10 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 **(Attachment A)**. Focus groups are valuable in exploring consumer reactions to design and message concepts before additional resources are put into their development.

Proposed Focus Group Study Design, Methodology, and Limitations

NCI will use a contractor, the Academy for Educational Development (AED), to conduct data collection activities. Twelve focus groups will be divided among three markets that are geographically dispersed. Two of the three markets have been determined and will be Washington, DC and Chicago, IL.

The focus group target audiences are as follows:

3 National Survey, 2006; Charlton Research Company for Research!America; http://www.researchamerica.org/uploads/poll. clinicalresearch.pdf

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

Audience	# of Focus Groups (# of participants)
General Public	2 (16) In 2 markets
Persons who have a family history of a serious illness that has limited standard care	2 (16) In 2 markets
Caregivers/family members of persons with long term chronic/terminal illness	2 (16) In 2 markets
Persons with long term, chronic/terminal illness	3 (24) In 3 markets
Cancer Survivors	3 (24) In 3 markets
TOTAL	***12 (96)*** ***In 3 markets***

* Each focus group will have 8 participants.

Research show that individuals do not give much thought to treatment clinical trials and their attitudes toward them unless they are concerned about a specific disease treatment (i.e., either they or someone close to them is sick or at greater risk). For that reason, four of the five focus group audience segments will be made up of persons who have such concerns. Three of these audience segments will be made up of people who personally have or did have a disease/medical condition for which clinical trials are an important source of improved treatment, while the fourth segment will consist of caregivers or family members of persons with long term chronic/terminal illness. The fifth audience segment will be the general public to ensure that any messages created will not have an unintended negative responses among individuals not impacted directly by a serious disease..

Specifically, focus groups participants will be screened on several key dimensions. Two groups each will be conducted with the following segments: a) persons who have a family history of a serious illness with limited treatment options, including those who may have personal concerns or fears for their family members (e.g., those with a family history of Alzheimer's disease); b) the general public, including those who do not have a serious, chronic or terminal illness and are not caregivers of persons with serious, chronic, or terminal illness; and; c) caregivers or close family members of persons with a serious chronic or terminal illness. We will conduct three groups each with the following segments: a) cancer survivors who have recently completed treatment and b) persons with a non-cancer long term, chronic, or terminal illness (e.g., persons with Parkinson's disease, Multiple sclerosis, diabetes, sickle cell, lupus, etc.). Focus group participants will include a diverse mix of adults aged 30 to 65 and of men and women. Participants with a diverse mix of education and race/ethnicity will also be sought. Because of the history around unethical clinical research specifically affecting African Americans (e.g., Tuskegee), two of the groups--one with cancer survivors and one with persons with long term, chronic/terminal illness will be conducted with African-American participants only to explore the potential differences on how the messages might impact them. The focus groups will be in-person and will be conducted by a professional moderator.

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. The focus groups will be audio taped, but the recording will be used primarily to verify specific quotes. Names and images will not be recorded, nor will personal identifying data be maintained. The primary analysis documents are the detailed observation notes. If more rigorous analysis is later needed, the tapes are available for transcription. Analysis will include the identification of key findings and overarching themes which will be presented in a report to NCI.

Recruiters will use a screening questionnaire (screeners) to identify eligible respondents in each category **(Attachment B)**. The screeners are carefully thought out so that the questioning process is short, easy to-understand, friendly, and efficient. In addition, the moderator guide for the focus groups will be used to ensure that the questions are easy to understand and answer, well-organized, and flow well **(Attachment A)**. Once eligible respondents have been identified, they will be asked to sign a consent form **(Attachment C)**.

The moderators will also be instructed to keep each group discussion under 120 minutes to limit burden to the respondents with respect to their time. Participation will be voluntary and respondents will be asked to participate only once.

Focus group participants will receive an incentive of $100 for their time and as a thank you for participating. Research on participation in focus groups indicates that, without providing minimal levels of incentive, insufficient numbers of participants will attend and results will not be useful. Light refreshments will also be provided to focus group participants.

AED will exclude any personal identifiers from data records. Participation will be strictly voluntary and individual respondents will not be identified. Any necessary identifying or potentially identifying information (e.g., signed consent agreements) will be secured and kept separate from the data records. Focus group respondents will be assured that neither their participation/non-participation nor any responses to items will have any effect on their eligibility for, or receipt of, services.

All information provided by respondents will be maintained in a confidential manner, unless compelled by law. AED 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 and AED'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.

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 246 respondents, of which 96 will participate in twelve focus groups with eight or fewer respondents per group. For each focus group, 10 individuals will be recruited and, based on prior focus group experience, it is expected that eight individuals appear for the group. To ensure that we accurately reflect a maximum burden potential, we are estimating the burden total on the assumption that 8 will attend each group. An average total participation time will be 120 minutes for focus groups; an additional ten minutes will be the average time allocated for recruitment of each participant. This culminates in a maximum total hour burden of approximately 208 hours (see Table below). The total annual burden approved for this generic study was 7050 and this sub-study accounts for less than 3% of the burden for this package.

Estimates of Hour Burden				
Respondents	Number of Respondents	Frequency of Response	Average Response Time (Minutes/Hours)	Annual Hour Burden
Screener (Attachment B)	150	1	10/60 (0.16)	25
Focus group participants (Mod Guide Attachment A)	96	1	120/60 (2)	192
Totals	246			217

Thank you for your consideration of this proposed sub-study.

Attachment (attached below):

5C) Focus group participant consent form

Attachments (in a separate file):

5A) Focus group moderator guide

5B) Focus group screener

Attachment 5C: Informed Consent Form

Identification of Project Statement of Age of Subject	**Testing of Messages for an NIH Clinical Trial Public Awareness Campaign** 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 gain insight into attitudes about and understanding of clinical trials and to determine reactions to messages developed to raise awareness of the importance, need and benefits and clinical trial participation to the public's health.
Procedures	Participants will be asked to join an in-person focus group at which point they will be asked a series of questions about their understanding of and attitudes toward clinical trial participation as well as their preferences for content and design of messages about clinical trials. The total time involved, including instructions, will be no more than 130 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 audio-recorded. My voice recording will not be played to others besides the research team without my written permission. The recordings will be kept in a secured location and will be destroyed by December 31, 2014.
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 but that the investigators hope to learn about preferred content and messages about clinical trials and clinical trial participation. With this enhanced understanding investigators will develop a communication campaign to increase awareness about clinical trials so that they can be more efficiently and effectively undertaken. I am free to ask questions or withdraw from participation at any time and without penalty.
Contact Information of Investigators	Associate Director, Office of Market Research and Evaluation, National Cancer Institute Telephone: 301-594-8193 Email: massetth@mail.nih.gov

Printed Name of Research Participant _____

Signature of Research Participant _____

Date_____