



Date: **December 15, 2010 (changes, based on OMB comments, highlighted in yellow)**
(Originally Submitted November 5, 2010)

To: Office of Management and Budget (OMB)

Through: Seleda Perryman, DHHS Report Clearance Officer
Mikia Currie, NIH Project Analyst, OPERA
Vivian Horovitch-Kelley, NCI OMB Project Clearance Liaison Office

From: Nina Goodman, Project Officer
Office of Communications and Education (OCE)
National Cancer Institute/NIH

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, “Survey to assess communications designed to raise awareness of clinical research” Proposed OMB No. 0925-0046-06

The National Cancer Institute (NCI) proposes conducting a web-based survey to determine which message concepts are best received by members of the general public and the medical community to raise awareness for each of the following areas:

- a. Importance of NIH-supported clinical research to public health,
- b. Need for clinical trial participants, and
- c. Benefits of clinical trial participation for the public’s health.

This research consists of administering a web-based panel survey designed to formatively evaluate and refine a number of communication approaches or concepts. The study will examine how different combinations of message elements and executional factors (such as imagery, tone, etc.) impact both the acceptance of key awareness/education themes for each concept and the participants’ intent to recommend or participate in clinical trials.

The content for the communications concepts that will be tested will be informed by findings from an earlier focus group research effort conducted by the Academy for Educational Development (AED) for NCI (Proposed sub-study OMB No. 0925-0046-05). Findings from this study will be used to develop a series of approximately three to five different creative approaches each for the general public and medical audiences.

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 patient¹. 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 performed². 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 research³. The NIH is interested in developing a public communication campaign to increase awareness of the three areas listed above.

Background information on Web surveys

Web-based surveys represent a standard state-of-the-art formative testing methodology, adapted from marketing and communications research. For this formative research, a self-administered web-based survey will be used, as it is a methodology frequently used to pretest drafts of concepts and materials that is both reliable and efficient. This survey will be accessed on-line at a designated and secure Internet location.

We will partner with ResearchNow to access their panel of respondents, including both members of the general population as well as specialty professionals of interest. ResearchNow is a leading global online sampling and online data collection company, recognized for delivering high-quality panelists, high response rates, and industry-leading panel retention rates. Our subcontractor on this study—Salter>Mitchell—has used them many times in the past on other studies similar in scope.

Methods

For this formative research, NCI proposes conducting a web-based panel survey with members of two main target audiences:

1. The adult (18+) general public,
 - a. This segment will include a over-sample of African Americans so that we can make observations and conclusion specifically about this sub-group of interest. Even in a non-probability sampling method, the proportion of racial and ethnic groups will be similar to the population at large. As such, African Americans would naturally be a relatively smaller group. The over-sample will provide a more robust sample size to analyze.
 - b. This segment will also include sub-groups of individuals who suffer from serious health conditions (e.g., Alzheimer’s, cancer, heart disease, diabetes, hypertension) and those who care for individuals with these conditions
2. Members of the medical community
 - a. This will include a mix of primary care physician, internists and general practitioners.

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>

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

Because the purpose of the current survey is to collect information to aid the development of communication message concepts, the sampling methods will focus on obtaining, with the greatest efficiency possible, feedback from targeted audiences and will therefore not use a probability sampling method. To this end, the survey will be conducted among members of a professionally-managed web-based survey panel. Panel members have experience conducting online surveys, have already indicated an expressed interest in completing web-based surveys, and have explicitly agreed to participate in surveys presented to them about issues both unrelated and related to health. As such, it is not uncommon for response rates on panel surveys to be notably higher than comparable studies conducted through a random-digit phone survey for example. Panel members are incentivized where each participant receives a small monetary award (\$1-5, determined by survey length, interest, complexity and the topical expertise) per survey. Once panelists' reward balance reaches \$10, they redeem a voucher with retailers in their region.

ResearchNow utilizes a multi-mode approach to recruiting members of its online panel. Specific to this study, they combine email, fax, and direct mail to recruit physicians to participate in online surveys (**Attachment 6A**). This approach provides a greater reach into the U.S. physician market; in total ResearchNow has access to more than 95% of all U.S. physicians. In addition to recruitment methods, they also purchase key association and governmental databases that verify a physician's practicing status. These verification resources include the Drug Enforcement Agency number (DEA#) and the American Medical Association (AMA) Medical Education Number (ME#).

Panel members eligible to participate in the current survey will be contacted through an e-mail invitation from the panel managers which will include a secure, non-identifiable link to the web-based survey (**Attachment 6B**). Recruitment will continue until the target sample size for completed surveys is reached.

Participants will be asked to answer a brief, self-administered, interactive web-based survey which includes a review and comparison of selected creative executions.

Specific measures on the survey will include the following (**Attachment 6B**):

1. Qualification/classification criteria
 - a. Conditions suffered from/caregiver status (non-medical audiences)
 - b. Practice type/conditions treated (Medical audiences)
2. Current awareness/knowledge/perceptions of clinical trials research (non-medical audiences)
3. Current perceptions toward and frequency recommending clinical trials research to patients (Medical audiences)
4. Exposure and reactions to the communications concepts individually

OPEN-ENDED QUESTIONS

- a. Main idea
- b. Positive/negative/confusing

SCALE/RATINGS QUESTIONS

- c. Believability/credibility
- d. Relevance—talks about things that are important to me
- e. Provides new information

- f. Likelihood of taking action (makes me want to volunteer/recommend, looking for more information, etc.)
- g. Emotional impact (surprises me, gives me hope, etc.)
- 5. Comparative ranking exercise for all assessed communications
- 6. Reasons for rankings OPEN-ENDED
- 7. Socio-demographics (age, sex, education, income)

We propose a total sample size of 450 for the general public and 150 for the medical community. This culminates in a maximum total hour burden of approximately 151 hours (see Table below). The total annual burden approved for this generic study was 7050 and this sub-study accounts for 2% of the burden for this package.

Estimates of Hour Burden				
Types of Respondents	Number of Respondents	Frequency of Response	Average Response Time (Minutes/Hour)	Annual Hour Burden
General Public (Attachment 6B)	450	1	15/60 (0.25)	113
Medical Community (Attachment 6B)	150	1	15/60 (0.25)	38
Totals	600			151

The margin of error for the general public sample will be approximately 4.6% at a 5% margin of error. The comparable figure for the medical sample will be 8.0%. Additionally, when comparing our main sub-groups of interest (general public/sufferers and caregivers/primary care physicians) we will need to observe differences of approximately 10% to note statistical significance.

Having noted that, statistical precision is not of foremost importance for this formative research effort. Our goal is to prioritize and refine potential communication concepts in order to maximize the chances that final creative executions will be successful. As such our total sample size was chosen based on the minimum number of participants required for reliable inferences to be drawn to guide final NCI decision-making regarding the concepts.

Individual respondents will not be identified and participation will be strictly voluntary. Names or images will not be recorded, nor will personal identifying data be maintained, nor will any responses to items will have any effect on their eligibility for, or receipt of, services.

All data will be collected by the contractor, the Salter>Mitchell, and all personal identifiers will be excluded from the data records. Any necessary identifying or potentially identifying information (e.g., signed consent agreements – **Attachment 6C**) will be secured and kept separate from the data records. All information provided by respondents will be maintained in a confidential manner, unless compelled by law.

Any data files that are delivered to NCI will be analyzed in the aggregate and no identifiable individual respondents will be provided. NCI Institutional Review Board (IRB) Research Integrity Officers will review the research instruments and ensure that all necessary human subject protection procedures are in place.

Thank you for your consideration of this proposed study.

Attachments (attached below):

6A) Email and Mailed Invitations

6C) Consent Form

Attachment (in a separate file):

6B) Web-based survey

Attachment 6A: Email Invitation

Subject Line:

Get e-Rewards as a Thank you for Your Time – Health Study

e-Mail Copy:

Dear <%First%>,

Based on your e-Rewards profile, you are invited to earn e-Rewards Currency for participating in a research survey. If you qualify and complete the survey:

Full reward amount: \$XX in e-Rewards Currency

Full survey length: approximately 15 minutes

To complete the survey and earn e-Rewards Currency, simply click the link below, or copy the URL into your browser:

[insert http: link]

We encourage you to respond quickly -- this e-Rewards invitation will be available only until a predetermined number of responses have been received. Please Note: you will only receive e-Rewards credit for taking the survey once.

Continue to check your inbox and your Member home page for future opportunities to earn e-Rewards Currency.

We value your time,
The e-Rewards Team

=====
Update your profile, review your account status, or cancel your membership online at: <http://www.e-rewards.com/myaccount.do>

=====
If you have an inquiry or experience problems with this message, please contact Member Services online at: <http://www.e-rewards.com/contactus.do>
or e-mail us at info@e-rewards.com.

Please do not reply to this e-mail.

=====
Read our Privacy Policy: <http://www.e-rewards.com/privacypolicy.do>
Read our Member Agreement: <http://www.e-rewards.com/memberagreement.do>

(C)2007 e-Rewards, Inc. 8401 N. Central Expressway, 9th Fl., Dallas, TX 75225 All rights reserved. e-Rewards and the e-Rewards logo are registered trademarks of e-Rewards, Inc

Attachment 6A: Mailed Invitation

Date

Name

Address

City, ST Zip

RE: 15 Minutes – Health Study for \$XX Honorarium –

Name:

e-Rewards® Medical Market Research, a leading provider of market research services to the professional healthcare community, would like to invite you to participate in a market research study.

Topic: Health Study

Cash Honorarium: \$XX.00

Length of Survey: 15 Minutes

Complete By: date

To access the survey, please enter the entire Web address below into your Web browser address bar. When prompted, please enter your PIN. Please note that the PIN is case-sensitive and must be entered exactly as shown.

Web Address: URL

PIN: PIN

Invite Code: CODE

We encourage you to respond quickly as this invitation will be available only until a pre-determined number of responses have been received.

The cash honorarium will be given to all participants who qualify and complete the full survey. Qualified participants will receive the cash honorarium only once for completing the survey. Your honorarium will be mailed 4-6 weeks after survey completion.

Thank you for your input.

Sincerely,

Attachment 6C: Informed Consent Form

Identification of Project

Health Study

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 a program of research being conducted by Salter>Mitchell via the online survey company e-Rewards.

Purpose

The purpose of this research is to gather information about health related topics that may inform the eventual development of marketing and communication materials.

Procedures

Participants will be asked to answer a series of questions on health topics, and also to review a series of creative materials on health topics and to provide their comments.

The total time involved, including instructions, will be about 15 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. My name will not be used.

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 use the research findings in order to develop communications that may benefit people more broadly, myself included. I am free to withdraw from participation at any time and without penalty.

Contact Information of Investigators

Name: Holly Massett, PhD
Position: Associate Director, Office of Market Research and Evaluation, OCE, NCI
Email: massettth@mail.nih.gov

I have read and understand this agreement:

- yes
- no

Printed Name of Research Participant _____

Signature of Research Participant _____

Date_____