DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
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Date: December 11, 2008

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Subject: **Generic Sub-Study, "Assessing Survivors' Cognitive, Affective and Information-Seeking Responses to Different Formats to Communicate Cancer Survival Statistics" (OMB No. 0925-0589-01)**

The National Cancer Institute (NCI) proposes conducting a small-scale pilot investigation to identify which communication formats might elicit the most optimal cognitive, affective (emotional) and information-seeking responses among prostate and colon cancer survivors. Background information on the study was detailed in a pre-submission memo sent on October 31, 2008 for the proposed generic sub-study, "Assessing Survivors' Cognitive and Affective Reactions to Different Formats to Communicate Cancer Survival Statistics" (OMB No. 0925-0589-01).

The information gathered from the pilot investigation will allow the NCI to better understand how cancer survivors perceive, understand and react to different ways of presenting complex cancer survival statistics. The information we learn from this pilot test will aid in the development of survey questions to assess these reactions on a population level.

Background on Project

Thanks to advances in cancer detection and treatment over the past 30 years, there are nearly 12 million cancer survivors currently living in the United States. This number is expected to rise dramatically over the next 20 years because the population is aging rapidly and cancer is largely a disease of older people. Improving survival from cancer is undoubtedly a public health success, but it is also important to attend to the cognitive, emotional and information needs of cancer patients and survivors.

Data from the 2005 administration of the Health Information National Trends Survey (HINTS) revealed that most cancer survivors and their families have sought cancer information, and many

have used the Internet to do so. There are millions of websites that provide cancer information, and this number is likely to grow over the next five years as the population ages and demand for such services increases. These websites have the potential to improve consumer engagement in medical decision making, but many websites do not communicate health information in a way that is comprehensible to laypeople. Misunderstanding the information presented on websites might lead people to experience negative consequences that were not anticipated by the website developers, such as inappropriate use or avoidance of the healthcare system.

Websites are increasingly providing cancer survival statistics to the public, but no published research has examined the cognitive, affective and information-seeking consequences of providing these statistics to cancer patients and survivors. In order to study this issue systematically and in detail, population-based survey research should be conducted. However, due to the sensitive nature of this topic, it is imperative that cognitive testing is conducted prior to including any cancer survival information in population-based surveys such as the Health Information National Trends Survey (HINTS). We plan to conduct this testing among cancer survivors.

Background Information on Pilot Testing

As discussed in the Supporting Statement for project 0925-0589, pilot testing and other small-scale studies are used to obtain insights into target audience attitudes and responses in the early stages of survey development (i.e., in concept, strategy and materials development). Pilot tests can also identify potential problems with the survey questions or visual displays. They are usually composed of people who have characteristics similar to the target audience, or subgroups of the target audience. Pilot tests are valuable in exploring consumer reactions to message concepts before additional resources are invested in their development.

Proposed Research for Assessing Cancer Survivors' Cognitive and Affective Reactions to Different Formats to Communicate Cancer Survival Statistics

NCI proposes conducting a small-scale pilot investigation to identify which communication formats might elicit the most optimal cognitive, affective and information-seeking responses among 2- to 10-year prostate (N = 200) and colon (N = 100) cancer survivors. Participants will be asked to complete a brief, self-administered, interactive web-based survey that shows different simulated outputs from a cancer survival statistics tool. Participants will see one of twelve alternative outputs which vary according to:

- the specific cancer survival situation: survival statistics that are based on nonspecific population-based data (standard practice) *vs*. survival statistics that include a high risk of mortality from diseases other than cancer, *vs*. survival statistics that include a low risk of mortality from diseases other than cancer;
- the type of visual display: 10 x 10 array of shaded stick figures *vs*. 10 x 10 array of shaded blocks; and
- the timeframe for survival: a single-graph that shows 5-year survival *vs*. multiple graphs that show 1-, 5- and 10-year survival.

The pilot test will examine how comprehensible the information is, as well as how the information affects survivors' cognitions (thoughts), emotions and information-seeking behavior

(i.e., how many people seek additional cancer information from NCI). Survivors' responses to this information will inform future population-based research on perceptions of cancer survival information.

The participants in this pilot investigation will be colon and prostate cancer survivors over the age of 18 who were diagnosed in the years between 1999 and 2007. The sample will include both men (prostate and colon cancer) and women (colon cancer), and will represent all racial, ethnic, and educational backgrounds. Participants for the pilot investigation will be recruited by Nexcura, a business of Thomson Reuters Healthcare. NexCura hosts and maintains free, Web-available patient education tools (the Profiler tools) that require registration with an email address and zip code, acceptance of a Terms and Conditions agreement and the option to receive email messages about, amongst other topics, research surveys. NexCura uses the information provided by survivors when they register to specifically target email messaging only to survivors' for whom the messaging is relevant. NexCura will send out an email to the target population with a brief summary of the research and a link to the survey. Survivors who agree to participate will complete the screener (see Appendix A) and the survey (see Appendix B). At the end of the survey participants will be redirected to a page hosted by NexCura in order to collect participant contact information for incentive purposes.

Participants will be asked to complete only one survey. Survivors who do not respond the initial recruitment email will be contacted again after one week. Survivors who do not respond to the second email will be contacted again one week after the previous recruitment attempt. If survivors do not respond after three recruitment attempts (i.e., initial contact, 1st recruitment attempt, 2nd recruitment attempt) no further recruitment attempts will be made.

Individual participants will not be identified and participation will be strictly voluntary. Personal identifying data will not be collected. Participants will be assured that neither their participation/non-participation nor any responses to the questions will have any effect on their eligibility for, or receipt of, services.

All data will be collected by the contractor, Westat. All information provided by respondents will be kept in a confidential manner to the extent permitted by law. NCI and Westat'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.

All respondents in the pilot testing groups will receive modest remuneration at a flat rate of $20. Research on participation in Internet-based studies indicates that, without providing minimal levels of monetary compensation, insufficient numbers of participants will participate and the results will not be useful. The amount of remuneration was determined by NexCura, and represents the minimal amount of funds necessary to make participation attractive to participants and to provide nominal compensation for their time and effort. This remuneration amount is also consistent with the Terms specified by OMB, for work done under Generic Clearance.

Data will be analyzed by using a statistical approach. For each of the three major variables, a regression analysis will be conducted to determine which communication format elicits the highest levels of understanding, the least anxiety, and the most requests for additional

information (i.e., how many people click on a link to the NCI's "Cancer Topics" webpage). The key findings will be presented in a report to NCI.

There will be a maximum of 300 respondents (12 groups with maximum of 25 individuals per group) and with an average total participation time of 0.33 hours (20 minutes). This includes 2 minutes for having the respondents complete the recruitment screener, read and provide consent, and 18 minutes to complete the pilot test survey. For each group, 25 individuals will be recruited based on having a diagnosis of colon or prostate cancer between 1999 and 2007. This culminates in a maximum total annual hour burden of 100 hours. At an average of $17/hour, the annual respondent cost is estimated at $1,700 for this sub-study.

Estimates of Hour Burden and Respondent Cost						
Types of Respondents	Number of Respondents	Frequency of Response	Average Time Per Response (Hours)	Annual Hour Burden	Hourly Wage Rate	Annual Respondent Cost
Cancer survivors	300	1	0.33	100	$17	$1,700

The full generic study, approved on May 21, 2008, requested a total of 600 burden hours. There have been no previous sub-studies approved by OMB under this umbrella submission. Approval by OMB of this sub-study would bring the total burden hour requested to date for 0925-0589 to 100; well below the original request of 600 hours.

Thank you for your consideration of this proposed sub-study #1.