



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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Subject: “Assessing of Cancer Information Service (CIS) Client Actions after being given Clinical Trials Information from Cancer Information Specialists”
(OMB No. 0925-0046-02; Expiration Date XX/XX/2016)

Background, Need and Use of Information

The information collection request described in this memo supports the National Cancer Institute (NCI) Cancer Information Service (CIS) in the Office of Public Information and Resource Management (OPIRM) in the Office of Communications and Education (OCE). This sub-study will focus on the effect of patient education offered by the CIS on client’s decisions about sharing information with physicians, treatment choices, and clinical trials participation.

The CIS is a trusted source for the latest, most accurate information on cancer in language that is easy to understand. Clients can contact the CIS through Live Chat, e-mail, or phone. For over three decades, CIS has been providing patients, their family members, and friends with cancer information, education and individualized clinical trials searches. Trials can be for treatment, prevention, detection, or palliative care. The CIS conducts a careful assessment of the patient’s cancer situation during an initial call and can proactively offer to conduct a search of trials for a particular cancer type. CIS cancer information specialists explain what clinical trials are, what constitutes phases of clinical trials, and offers to send free print material and a tailored clinical trials search. Patients are encouraged to share the information with their physician to determine if they are eligible for a clinical trial. It is not known, however, how many patients actually do share the information with a physician, consider participating in a clinical trial, or enroll in a

clinical trial, or how much the CIS interaction and information may have influenced their decisions.

The first step in addressing the aforementioned challenges is to closely examine how CIS clients/patients are using the information received, their actions after receiving it, and their interactions with the physician about clinical trials. This formative research will help the CIS determine what action(s), and for what reason(s), a client takes regarding clinical trials after speaking with a CIS cancer information specialist and receiving clinical trials information. The knowledge gathered from the survey will help to establish baseline measurements to inform process improvements in the Cancer Information Service program, i.e. modifying the training for CIS cancer information specialists and improving customer service.

Participants

The sample size for this survey will be 344 clients who received information from the CIS about clinical trials. The sample will consist of clients who contact the CIS either by phone, email, or Live Help over a period of 6 months. Cancer information specialists already routinely assess the situation of each client and, when appropriate, conduct clinical trials searches, explain the clinical trials process, offer to send printed information, and encourage clients to discuss information with their doctor. Any client who receives clinical trials information (either by phone, by email, or agrees to have the printed material sent to them) during this 6-month period is eligible to participate. During this period the respondents who contact CIS by phone will be asked if they would like to participate in a voluntary on-line survey and then consented by the cancer information specialist (**Attachment A**). Respondents who contact CIS through email, will be sent the same information as in Attachment A and clicking on the link indicates consent. The sampling frame will consist of all clients contacting CIS during the 6-month period that received information about clinical trials and volunteered to participate in the survey.

Research Instrument

The attached draft online survey (**Attachment B**) form will be used as the research instrument. The University of Massachusetts/Donahue Institutes, a contractor, will be collecting this information on behalf of NCI. NCI has previous experience working with this research team.

Methodology

The survey will have 26 questions and collect information on topics such as the understandability of the information, the use of the information, how doctors used the information, and whether the information influenced the decision to participate in clinical trials. The survey will be conducted over a rolling 6-month collection period.

Quantitative/descriptive analysis will be done on the survey. The demographic profile of the types of clients who receive clinical trials information from the CIS will be assessed and described. Comparisons will be made across demographic groups which will help the CIS determine if any tailoring of program components to demographic groups of clients would improve the service. Demographics of interest may include gender, educational level, and the relationship of client to patient, area of the country, ethnicity, age range, and method of contacting the CIS. This information, though not part of the current survey, can be obtained from

the information already gathered during the CIS contact (OMB No. 0925-0208, approved 12/21/2012).

Other Considerations

The Office of Human Subjects Research Protection (OHSRP) has reviewed this project and determined that it is exempt (**Attachment C**). The NIH Privacy Act Officer, will be asked to review the sub-study for PII and Privacy Act applicability.

Estimates of Hour Burden and Respondent Cost					
Types of Respondents	Instrument	Number of Respondents	Number of Responses Per Respondent	Average Time Per Response (in hours)	Total Hour Burden
Patients, friends, family, general public	Survey	344	1	10/60	57
Total					57

List of Attachments

- A. Script, Email and Consent
- B. Screenshots of Survey questions
- C. Office of Human Subjects Research Protection (OHSRP) Review