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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Subject: Online Needs Assessment Survey to Inform the Development of Tools and Materials to Further NCI-designated Cancer Centers' Clinical Trial Accrual Practices (OMB No. 0925-0046-18; Expiration Date 1/31/10)

The National Cancer Institute (NCI) proposes conducting a Web-based survey with representation from a range of personnel at NCI-designated cancer centers to help inform the development of materials and tools that will support increased accrual to clinical trials. The goal of this formative needs assessment is to better understand the prevalence of promising practices to support accrual to clinical trials. These assessment data will be collected from and analyzed among and within responding institutions. The current research design will focus on collecting data from persons in the cancer centers who have day-to-day responsibility for clinical trial accrual and who are in a position to know about how accrual functions in their center.

Background

Despite the potential benefits to participating in cancer clinical trials, fewer than 10% of cancer patients enroll in trials around the country.[1] As a result, numerous trials (by some estimates 28-68%) fail to accrue any or enough patients to produce sufficient data to address the trials' hypotheses[2], ultimately hindering potential advancements in fighting cancer and consuming a substantial amount of resources with limited outcomes. There is a plethora of research published on benefits and barriers to accrual, but there are few evidence-based best practices around the process of improving clinical trial accrual. The National Cancer Institute's (NCI) Office of Communications and Education (OCE) has a committed effort to assist with clinical trial accrual. In 2006, a series of interviews with key individuals across NCI's divisions, offices and centers (DOCs) also pointed to OCE as the NCI office that should be proactively addressing the communication and education needs around recruitment and accrual into clinical trials. In response, OCE

1 Paskett, E.D., Cooper, M.R., Stark, N. et al. (2002) Clinical trial enrollment of rural patients with cancer. *Cancer Pract*, 10:28-35
2 Dilts, D. M., Sandler, A. B., Cheng, S., Crites, J., Ferranti, L., Wu, A., Bookman, M. A., Thomas, J. P., & Ostroff, J.. (2008). Accrual to clinical trials at selected comprehensive cancer centers. *J Clin Oncol* 26 (May 20 suppl)

has undertaken a number of efforts to better understand best practices around clinical trial accrual and the communication needs and processes of those in the field to increase trial participation.

During 2007, OCE commissioned a literature review summarizing best practices for clinical trial recruitment as published in the peer-reviewed literature. A key finding from this literature review was how few evidence-based practices are available in the published literature, with most practices showing potential to be effective in recruitment but with limited evidence. This point was confirmed in follow-up conversations with stakeholders from major provider associations when asked for their expert opinion on the literature review findings and on accrual efforts to cancer clinical trials overall.

As a follow up to the literature review, OCE held conversations with Community Clinical Oncology Program (CCOP) staff who attended the spring meeting of the North Central Cancer Treatment Group (NCCTG) and the Southwest Oncology Group (SWOG) to explore qualitatively their best practices in the recruitment process, and identify areas where NCI can provide them additional support. OCE also conducted three case studies of comprehensive cancer centers located in different parts of the country and operating under different contextual circumstances. The selection of the sites was guided by criteria that included success at clinical trial accrual. These case studies qualitatively document clinical trial accrual practices across the comprehensive cancer centers, detail their processes, and identify promising practices that lead to successful patient accrual within a center.

In order to determine where NCI should invest its communication and education efforts directed at cancer centers, it is imperative to first narrow down the list of promising practices based on quantitative formative research that can be generalized across NCI-designated cancer centers. Using a framework developed through the formative work to date, OCE proposes conducting a Web-based survey to further explore which promising practices that were identified in the three case studies are related to higher accrual. The survey will explore the extent that cancer centers are doing each promising practice, and responses will analyzed against the centers' annual clinical trial accrual rates.

Methodology

NCI proposes a Web-based survey. To date there are 65 NCI designated cancer centers—40 are comprehensive cancer centers and 25 are cancer centers. NCI proposes including all 65 NCI-designated cancer centers in the sampling frame. We will send survey invitations to the following persons in each cancer center:

- Clinical trial outreach coordinator
- Director of Hematology Oncology Department
- Lead Research Nurse in Hematology Oncology.

The proposed Web-based needs assessment survey will consist predominantly of close-ended questions. To provide contextual insights, several open-ended questions will also be asked. The approximate time required to complete the survey will be 15-20 minutes.

The invitation letter will include information about the study as well as contain phone numbers and an email address where technical assistance and content clarification can be acquired, as needed. If the invited party would prefer to take the survey in hard copy, they will be instructed to email or call for a copy to be sent to them.

Invitations to participate will be sent by email, and working with the Cancer Centers' communication liaisons (each cancer center has a communication representative that works directly with NCI on

communication outreach activities). The invitation letter will explain the purpose of the survey, the formative nature of the needs assessment and how the survey results will be able to be used by them and by NCI to better support cancer centers' clinical trial accrual communications needs. The letter will also ask the liaison to provide NCI with the contact information for the other individuals in their cancer center who should take the survey. The liaison will be asked to send communications out to relevant staff informing them of the upcoming survey and impressing upon them the importance to their institution of the staff's fullest participation.

The Web-based survey will be housed on a secure site and will be 508 compliant. Survey administration and implementation will be provided by the Academy for Educational Development (AED), a contractor to NCI working with User Centered Design, Inc. as its sub-contractor who will assist with fielding the survey. A telephone number and email address will be provided for queries if the participant encounters any difficulties or requires any clarifications while responding to the survey. The telephone number will be answered 24 hours a day to minimize the burden on participants, ensuring that they can take the survey at their convenience. Email inquires will be responded to during normal working hours, EST.

A temporary survey database will be constructed with information about the survey invitees. The database will include participant name; institution name; title/position; log-on; and password. It will also include tracking information such as date invitation sent, date survey initiated, date reminders sent; date any questions were answered and date survey was completed. Once the survey has been completed, the fields containing participant name, log-on and password information will be eliminated and no copy of the database with this information will be maintained. After creation of the final report all process information will be deleted. And after a period of 5 years the logistical database will be destroyed.

Once the list of suggested participants is received from an institution, invitations to take the Web-based survey will be sent out by email. Participants will be sent a log-on and password. These will enable the participants to complete the survey in several sessions. This is important in case the participant feels the need to elicit information from others they work with – or asks others to fill out parts of the survey.

The survey will be accessible for 2 months. After the invitation to take the survey is sent, if a survey has not been completed, an email request to do so will be sent. These requests will be generated every two weeks. After six weeks, phone calls will be placed to administrators in instances where less than half the identified participants at their site have failed to complete their survey. Specific individual's names will not be given but a request will be made for the administrator to reemphasize the importance of the survey. Thank you emails will be sent out after surveys have been completed.

Responses to the survey will be confidential. After survey finalization and review, a respondent's name will be deleted from a tracking database. After the final report is completed all institutional identifiers will be disassociated from site names and the site names will be destroyed.

Research Instrument

The Web-based needs assessment will be conducted through a Web-based survey **(See Attachment A)** and has been developed after discussions with NCI researchers, administrators and staff at several comprehensive cancer centers, members and administrators of a pair of cancer clinical trial cooperative groups, and researchers in the area of cancer clinical trial administration and process. The goal of the needs assessment project is to identify the extent to which sites are using practices that appear, in some of the preliminary work, to be associated with higher clinical trial accrual rates.

The survey will address the following topic areas:

- Organizational Issues (e.g., leadership, mission/vision, accountability, culture, commitment, resource availability)
- Protocol Portfolio Management (e.g., development and selection of protocols, tracking, closure)
- Recruitment/Accrual Practices (e.g., staffing, training and promotion, patient screening, education)
- Information Technology
- Trial Reimbursement (e.g., health insurance, CMS)
- Community Outreach (e.g., physicians, minority and underserved)

Participants

Participants in this survey will be clinical trials outreach coordinators, the Director of the Hematology Oncology Department, and the Lead Research Nurse in Hematology Oncology in each NCI-designated cancer centers.

Participants will be invited to participate by email. We expect 3 responses per cancer center for a total of 195 participants. The survey should take each of the participants approximately 20 minutes (0.33 hours) to complete. The total respondent burden for this effort is 65 hours. This effort will account for 3.3 percent of the total annual burden hours (2010) granted in our approval package.

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
Stakeholders	195	1	20/60 (0.33)	65	$125	$8125.00

Please feel free to contact me at 301-435-7789 if you have any questions.

List of Attachments

A: Accrual Needs Assessment Instrument
B: Informed Consent Form