

GENERIC SUB-STUDY SUBMISSION – 0925-0046-20

DATE OF REQUEST: March 27, 2012

SUB AGENCY (I/C): OCE and CTEP

TITLE OF SUB-STUDY: Formative Evaluation of Concise Informed Consent Document (ICD)

GENERIC CLEARANCE UNDER OMB #0925-0046-20 **EXP. DATE:** 02/28/2013

TOTAL BURDEN APPROVED:	7050 hours
BURDEN APPROVED TO DATE:	2706 hours
BURDEN THIS REQUEST:	182 hours

ABSTRACT:

In 1997, the NCI developed a lay language Informed Consent Template for use in its cancer clinical trials. This Informed Consent Template complies with regulatory requirements in a low-literacy format and provides a structure and guidance on how to use lay language to create informed consent documents (ICDs) for NCI-sponsored trials. Overtime, however, use of the template has resulted in the creation of trial-specific consent documents that are generally too long and burdensome to patients. Working with experts from the field, NCI has recently developed a more concise template that it hopes will produce shorter, less burdensome ICDs.

NCI is planning to conduct a web-based panel survey with adult colorectal cancer survivors to determine whether the revised “concise” template makes it easier to understand and better meet the needs of people considering cancer clinical trial participation. As part of this formative evaluation, CTEP will develop an ICD for an existing trial using the concise template (an ICD would already exist for that trial using the original 1997 template). CTEP is planning to assess patient satisfaction and knowledge gained using the new concise ICD compared to the original ICD. Published literature also suggests that adding patient-friendly material about the trial (in addition to an ICD) increases patient satisfaction and knowledge gained.

IS RACE AND ETHNICITY DATA COLLECTED AS REQUIRED?

YES NO N/A

OBLIGATION TO RESPOND:

VOLUNTARY
 REQUIRED TO OBTAIN OR RETAIN BENEFITS
 MANDATORY

HOW WILL THIS SURVEY BE OFFERED?

WEB SITE
 TELEPHONE INTERVIEW
 MAIL RESPONSE
 IN PERSON INTERVIEW
 OTHER:

CONTACT INFORMATION:

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GENERIC SUB-STUDY SUBMISSION – 0925-0046-21

DATE OF REQUEST: March 7, 2012

SUB AGENCY (I/C): OCE and DCTD

TITLE OF SUB-STUDY: Revision of Rapid Feedback Tool to Identify Accrual Problems with Active NCI Clinical Trials

GENERIC CLEARANCE UNDER OMB #0925-0046-21 **EXP. DATE:** 02/28/2013

TOTAL BURDEN APPROVED: 7050 hours
BURDEN APPROVED TO DATE: 2706 hours
BURDEN THIS REQUEST: 0 hours (not asking for increase in burden since previously approved, just asking for approval of two new surveys)

ABSTRACT:

This sub-study originally received approval from OMB on June 15, 2011 (OMB No. 0925-0046-15). Two new surveys are being added, however no additional respondents or burden hours are being requested. These surveys were designed to seek feedback from the field about low accruing trials that had been open for at least a year. Low accrual to oncology clinical trials persists, with over 40% of National Cancer Institute (NCI) sponsored trials failing to achieve minimum accrual goals. There are three timeframes in a trial's life cycle where opportunities exist to positively impact a trial's accrual: 1) prior to a trial concept being approved; 2) during a protocol's development; and, 3) once a trial is open and running. NCI is interested in identifying potential accrual problems at the trial concept, protocol and implementation stage; and ultimately to determine if they are worthy to open, repairable or if they should be terminated (resulting in substantial resource and scientific losses to NCI).

OCE has developed four versions of a brief online feedback tool to assist CTEP to explore a concept's level of interest, a protocol's feasibility, and why a trial is poorly accruing. These tools are templates that can be tailored to a trial and sent to oncologists and research staff in the community who opened the trial.

IS RACE AND ETHNICITY DATA COLLECTED AS REQUIRED?

_____ YES NO _____ N/A

OBLIGATION TO RESPOND:

VOLUNTARY
_____ REQUIRED TO OBTAIN OR RETAIN BENEFITS
_____ MANDATORY

HOW WILL THIS SURVEY BE OFFERED?

WEB SITE
_____ TELEPHONE INTERVIEW
_____ MAIL RESPONSE
_____ IN PERSON INTERVIEW
_____ OTHER: _____

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GENERIC SUB-STUDY SUBMISSION – 0925-0046-22

DATE OF REQUEST: March 29, 2012

SUB AGENCY (I/C): OCE and DCP

TITLE OF SUB-STUDY: Formative Audience Research for Spanish Template Informed Consent Form

GENERIC CLEARANCE UNDER OMB #0925-0046-22 **EXP. DATE:** 02/28/2013

TOTAL BURDEN APPROVED: 7050 hours
BURDEN APPROVED TO DATE: 2706 hours
BURDEN THIS REQUEST: 50 hours

ABSTRACT:

Hispanics/Latinos are affected by many economic and cultural disparities in health care, including disproportionate participation in Federally-funded cancer research. In addition, lack of involvement in health research has hindered the development of prevention and treatment efforts for this special population group. This research supports ongoing efforts at NCI to increase participation of Latinos in clinical trials by developing culturally and linguistically appropriate clinical trials information, tools, and processes. Specifically, the current data collection will be used to improve and culturally adapt clinical trials informed consent documents and processes. In an effort to better meet the needs of potential Spanish-speaking clinical trials participants, NCI has culturally and linguistically adapted and translated the informed consent template into Spanish. For this purpose, in-depth interviews will be conducted with members of the Spanish-speaking population, to explore their thoughts and opinions regarding the informed consent template for chemoprevention clinical trials and to learn about promising practices related to the consenting process with potential Latino clinical trial participants. A qualitative analysis will be conducted by reviewing notes and audio recordings to identify themes and to ensure equal representation of diversity and viewpoints within the data. A topline report summarizing key findings and providing study implications and recommendations will be written.

IS RACE AND ETHNICITY DATA COLLECTED AS REQUIRED?

YES NO N/A

OBLIGATION TO RESPOND:

VOLUNTARY
 REQUIRED TO OBTAIN OR RETAIN BENEFITS
 MANDATORY

HOW WILL THIS SURVEY BE OFFERED?

WEB SITE
 TELEPHONE INTERVIEW
 MAIL RESPONSE
 IN PERSON INTERVIEW
 OTHER: _____

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