GENERIC SUB-STUDY SUBMISSION – 0925-0046-14

DATE OF REQUEST: April 18, 2011

SUB AGENCY (I/C): OCE

TITLE OF SUB-STUDY: In-Depth Interviews on NCI's "What You Need To Know About Breast Cancer" Booklet

GENERIC CLEARANCE UNDER OMB #0925-0046-**14** ***EXP. DATE:*** *02*/28/2013

TOTAL BURDEN APPROVED:	7050 hours
BURDEN APPROVED TO DATE:	1876 hours
BURDEN THIS REQUEST:	61 hours

ABSTRACT:
The National Cancer Institute's (NCI) Office of Communications and Education (OCE), Office of Market Research and Evaluation (OMRE) is planning to conduct in-depth interviews with breast cancer patients and survivors to inform revisions to the patient education booklet "What You Need to Know About Breast Cancer." These booklets, written in simple language, describe possible risks, symptoms, diagnosis, and treatment for breast cancer.

The in-depth interviews (IDIs) will be conducted with a total of 24 breast cancer patients/survivors. Prior to the interviews, participants will be mailed a copy of the booklet to read and review ahead of time. The interview will be conducted either in person or remotely (through web conference and/or phone) and will last no more than 60 minutes.

Feedback from breast cancer patients and survivors will help NCI assess the extent to which the booklet is meeting the expectations and needs of its audience and to identify ways in which the content of the booklet may be improved. The results from this research are not only expected to help inform NCI's revisions to this booklet, but to other similar booklets published by NCI.

IS RACE AND ETHNICITY DATA COLLECTED AS REQUIRED?
___X___YES _____NO_____N/A

OBLIGATION TO RESPOND:
__X___ VOLUNTARY
_____ REQUIRED TO OBTAIN OR RETAIN BENEFITS
_____ MANDATORY

HOW WILL THIS SURVEY BE OFFERED?
_____ WEB SITE
_____ TELEPHONE INTERVIEW
_____ MAIL RESPONSE
__X___ IN PERSON INTERVIEW
_____ OTHER:

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GENERIC SUB-STUDY SUBMISSION – 0925-0046-15

DATE OF REQUEST: April 18, 2011

SUB AGENCY (I/C): OCE and DCTD

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

GENERIC CLEARANCE UNDER OMB #0925-0046-15 ***EXP. DATE: 02/28/2013***

TOTAL BURDEN APPROVED:	7050 hours
BURDEN APPROVED TO DATE:	1876 hours
BURDEN THIS REQUEST:	152 hours

ABSTRACT:
Low accrual to oncology clinical trials persists, with over 40% of National Cancer Institute (NCI) sponsored trials failing to achieve minimum accrual goals. As of 2004, NCI has implemented an institute-wide effort to improve the operational efficiency of its clinical trial enterprise system. Recently, efforts have focused improving "running" a trial: many trials remain open despite abysmal accrual rates. NCI is interested in identifying problems with these trials to determine if they are reparable or if they should be terminated. Critical is the opinion of researchers in the oncology field, who accrue over 60% of patients to NCI's trials; yet, NCI has few mechanisms to seek their feedback and remain mostly connected to the academic researchers who develop the trial concepts but rarely accrue. OCE has recently developed a brief 15-question online feedback tool to explore why a trial is poorly accruing. This tool is a template that can be tailored to a trial and sent to oncologists in the community who opened the trial. There are two versions of this tool: for oncologists (to ask about the trial's science) and for research staff (to ask about its feasibility). OCE would like to pilot this tool for one year on two trials a month. NCI can use the report as part of their decision-making to run the trial. OCE will keep records of the trials over the year and determine the overall impact of the findings.

IS RACE AND ETHNICITY DATA COLLECTED AS REQUIRED?
_____YES __X___NO_____N/A

OBLIGATION TO RESPOND:
___X__ VOLUNTARY
_____ REQUIRED TO OBTAIN OR RETAIN BENEFITS
_____ MANDATORY

HOW WILL THIS SURVEY BE OFFERED?
__X___ WEB SITE
_____ TELEPHONE INTERVIEW
_____ MAIL RESPONSE
_____ IN PERSON INTERVIEW
_____ OTHER: _____

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GENERIC SUB-STUDY SUBMISSION – 0925-0046-16

DATE OF REQUEST: April 18, 2011

SUB AGENCY (I/C): OCE and DCTD

TITLE OF SUB-STUDY: A Pilot Study to Test a Proposed New Model for the NCI's CIRB Participating Institution

GENERIC CLEARANCE UNDER OMB #0925-0046-**16** ***EXP. DATE: 02/28/2013***

TOTAL BURDEN APPROVED:	7050 hours
BURDEN APPROVED TO DATE:	1876 hours
BURDEN THIS REQUEST:	431 hours

ABSTRACT:

The process to obtain IRB approval for new clinical trials has historically contributed to a delay in trial activation. As a result, NCI's Central Institutional Review Board (CIRB) program is considering changing its model of operation and adopting a new model to use with its 300+ enrollees. This change was recommended by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) for accreditation and improved efficiencies, but will require substantial resources for NCI to implement. NCI is first planning to pilot test the new model with 25 sites. As part of this pilot, NCI is planning to survey 3-5 IRB staff members at each site before, during and after the pilot study to identify areas of the new model that worked well or not. The survey link will be sent to participants via an email, filled out and submitted confidentially online. This information will be critical to determine if NCI should roll out the new model nationwide and invest the resources. Additionally, there are four forms that will be completed by the Principal Investigators.

IS RACE AND ETHNICITY DATA COLLECTED AS REQUIRED?
_____YES __X___NO_____N/A

OBLIGATION TO RESPOND:
___X__ VOLUNTARY
_____ REQUIRED TO OBTAIN OR RETAIN BENEFITS
_____ MANDATORY

HOW WILL THIS SURVEY BE OFFERED?
__X___ WEB SITE
_____ TELEPHONE INTERVIEW
_____ MAIL RESPONSE
_____ IN PERSON INTERVIEW
_____ OTHER: _____

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