**Mini Supporting Statement B For**

“A Generic Submission for Formative Research, Pretesting, and Customer Satisfaction of NCI’s Communication and Education Resources”

OMB No. 0925-0046-09, Expiration Date 05/31/2016

Title of Sub-Project:A Customer Satisfaction Survey of Participants in the New National Cancer Institute’s Experimental Therapeutics Clinical Trials Network (ETCTN)

December 2014

Holly A. Massett, PhD.

Senior Behavioral Science Analyst,

Cancer Therapy Evaluation Program (CTEP),

Division of Cancer Treatment & Diagnosis,

National Cancer Institute, National Institutes of Health

Attachments

Attachment #1: Principal Investigator Online Customer Satisfaction Survey

Attachment #2: Research Staff Online Customer Satisfaction Survey

Attachment #3: Invite and Reminder Emails

Attachment #4: OHSRP Determination Letter

# Section B. Statistical Methods

## B1. Respondent Universe and Sampling Methods

It is expected that 250 participants will be surveyed each year for two years (total N=500). All Experimental Therapeutics Clinical Trials Network (ETCTN) *Grant Principal Investigators* (N=30) and *Grant Administrators* will be surveyed (N=45) given their small population size. For all other roles where there are 75-150 persons per category (i.e., PIs and other research staff, including site administrators, clinical research associates and registrars) and who could potentially have little to no involvement in the program during its first grant years, we will use a purposive sample to survey only those who have participated in the ETCTN program processes of opening and/or accruing patients to an ETCTN trial over the previous grant year. These individuals can easily be identified via NCI’s Cancer Trials Support Unit (CTSU) which tracks all roster activity at ETCTN grantee organizations. We expect the sample to be: principal investigators who have been involved in opening a trial during the previous grant year (N=45); and other research staff (site administrators, clinical research associates, and registrars) who participated in the process over the past grant year (N=130).

## B2. Procedures for the Collection of Information

ETCTN staff will receive an initial email invitation (**Attachment 3**) to participate in one of the two online ETCTN satisfaction surveys (**Attachments 1 & 2**). This invitation will describe the purpose of the survey, approximate burden time, and privacy details. A link to the survey will be included in the email, where the individual will be directed to the survey landing page. The landing page will reiterate the description of the survey, approximate burden time, and privacy details. Instructions are also provided for respondents to continue to the survey.

The survey will be available for 2 weeks. If the individual does not complete the survey within the first week, a follow-up reminder email (**Attachment 3**) will be distributed the following week.

## B3. Methods to Maximize Response Rates and Deal with Nonresponse

We estimate a 95% response rate, based on a similar survey that was administered to NCI grantees about the Central Institutional Review Board program (OMB No. 0925-0046-16, Expiration Date 2/28/2013). Thus, we expect 238 participants to provide data.

Email reminders (**Attachment 3**) will be used to increase response rates. During the 2-week survey period, the initial invitation email will be sent the first week. If a participant does not complete the survey within the first week, a follow-up reminder email will be sent. This email reminder will provide a description of the survey, approximate burden time, privacy details, and a link to the survey.

## B.4 Test of Procedures or Methods to be Undertaken

Survey procedures and data capture will be tested two weeks prior to the launch of the survey. Any testing conducted will involve fewer than 10 respondents.

## B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

|  |  |
| --- | --- |
| Jennifer Huang, Ph.D.Senior Study DirectorWestat1600 Research Blvd, WB 424Rockville, MD 20850Phone: 301-610-5590Fax: 301-738-8379 Email: JenniferHuang@Westat.com | S. Percy Ivy, MDAssociate Chief, Investigational Drug BranchCancer Therapy Evaluation ProgramProgram Director, Experimental Therapeutics Clinical Trials Network (ETCTN)Division of Cancer Treatment and DiagnosisNational Cancer Institute9609 Medical Center Drive, Room 5-W458Bethesda, MD 20850Office: 240 276 6107Email: ivyp@ctep.nci.nih.gov |
| Grace Schroer, MPH, CHESPresidential Management Fellow, Class of 2016Current Rotation:9609 Medical Center Drive, RM 5W342Clinical Investigations Branch (CIB)Cancer Therapy Evaluation Program (CTEP)Division of Cancer Treatment and Diagnosis (DCTD)National Cancer Institute, NIH, DHHS email:  grace.schroer@nih.gov |  |