



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: November 27, 2012

TO: Office of Management and Budget (OMB)

Through: Keith Tucker, Report Clearance Officer, HHS
Seleda Perryman, Project Clearance Officer, NIH
Vivian Horovitch-Kelley, PRA OMB Project Clearance Liaison, NCI

FROM: Dr. Mike J. Montello, Pharm. D., CTEP (National Cancer Institute)
Mary Williams, B.S. (Westat)

SUBJECT: Nonmaterial/Non-substantive change request for:
Cancer Trials Support Unit (CTSU) Public Use Forms and Customer
Satisfaction Surveys (NCI), OMB #0925-0624, Expiration Date
12/31/2013.

This is a request for OMB to approve a nonmaterial/non-substantive change to two forms that are a part of the Cancer Trials Support Unit program. There are no changes in the purpose or objectives of the program or changes to the estimated usage. Additionally, none of the changes being requested are substantive or contain new elements.

The Cancer Trials Support Unit (CTSU) is a contractor operated service offered by the National Cancer Institute - Cancer Therapy Evaluation Program (CTEP) - to enhance and facilitate access to cancer clinical trials in the United States and Canada. The CTSU maintains a broad menu of trials developed by the cancer Cooperative Groups and other research consortia and works with these organizations to offer patient enrollment, data collection, data management, regulatory services, and enrollment reimbursement services to clinical sites entering patients in these trials. Westat is the prime contractor for this project.

As outlined in Supporting Statements A and B of the OMB package submitted in 2010 for the CTSU, a number of project specific forms are being used to facilitate data collection and processing. Forms are submitted by participating clinical sites to the CTSU as needed.

This request is to cover changes being made to two forms – Attachments 1e and 1cc. The summary of changes for the forms are described below:

Attachment 1e - Roster Update Form

The phrase “and associates” was added under Cooperative Group updates to clarify requirements for the addition of person to the CTSU roster. The CTSU requires investigators and associates to have active Cooperative Group or network affiliations. There are no anticipated changes to the frequency of use or time to complete this form.

Attachment 1cc – CTSU Transfer Form

Minor changes to the form were made to add transfer instructions for studies in OPEN and on the CTSU menu. The Data Share field was added to the form in order to incorporate transfers for studies that utilize the Rave Clinical Data Management System for data submission. There are no anticipated changes to the frequency of use or time to complete this form.