DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: August 17, 2011

TO: Office of Management and Budget (OMB)

Through: Mary Forbes, Report Clearance Officer, HHS
Seleda Perryman, Project Clearance Officer, OPERA, NIH
Vivian Horovitch-Kelley, PRA OMB Project Clearance Liaison, NCI

FROM: Dr. Mike J. Montello, Pharm. D., CTEP (National Cancer Institute)
Vicki Sadique, RN, BSN, CCRP (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 the Cancer Trials Support Unit program. Based on a teleconference with OMB on 10/7/2010, a nonmaterial/non-substantive change request is sufficient for the proposed addition. 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 quality 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.

Summary of Changes:

Attachment 1b - CTSU IRB Certification form
Minor changes to better emulate the workflow in the database. There are no anticipated changes to the frequency of use or time to complete this form.

These changes only reflect changes in the position of questions and minor wording changes (Questions 12, 14, & 15).

Question 12: Deleted "Meeting" and added "or Designee Review from box 10."
Question 14: Substituted "Date all contingencies were met:" with "Provide date all contingencies were approved by the IRB or Designee:"
Question 15: Substituted "Give date if this is an initial facilitated review" with "Give date of the initial facilitated review by the local IRB or Designee."

Attachment 1e - Roster Update Form
The information pertaining to CTSU Independent Clinical Research Sites (CICRS) sites is no longer applicable as that program is closed. In the past, there have been issues with identifying the individual who submitted forms to CTSU based solely on the person's signature, but addition of space for individual to write in their "CTEP ID" at the bottom of the form will enable the processor to better identify the individual submitting the form. There are no anticipated changes to the frequency of use or time to complete this form.

Attachment 1di - Site Addition Form
There is a new regulatory form that has not previously been submitted. This form is now being added to facilitate the addition of new clinical sites to an already existing IRB approval within a network. CTSU regulatory forms (**Attachments 1a-1d in original submission**) are required to maintain benefits of the program by ensuring that institutions participating in CTEP-supported clinical trials have received Institutional Review Board (IRB) approval. The use and purpose of the Site Addition Form is no different than the other regulatory forms already approved by OMB.

It is estimated that there will be very low usage of this form (approximately 25 burden hours per year) which is largely off-set by closure of data management work on the N0147 study. Estimated annual burden for the N0147 forms (Attachment 1j and 1k in original submission) was 2,150 hours per year.