



Date: March 2, 2015

To: Office of Management and Budget (OMB)

Through: Keith Tucker, Report Clearance Officer, HHS
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From: Dr. Mike J. Montello, Pharm. D., CTEP (National Cancer Institute)
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Subject: Nonmaterial/Non-substantive change request for:
Cancer Trials Support Unit (CTSUS) TAILORx Data Transmittal Form
OMB #0925-0624, Expiration Date: 1/31/2017

This is a request for OMB to approve a nonmaterial/non-substantive change to the Cancer Trials Support Unit Program (CTSUS). Based on a teleconference with OMB on 10/7/2010, a nonmaterial/non-substantive change is sufficient for this request as it does not change the purpose or objectives of the program or change the overall burden to the public.

The Cancer Trials Support Unit (CTSUS) 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 CTSUS maintains a broad menu of trials developed by the NCI-funded sponsoring networks and works with these organizations to offer patient enrollment, data collection, data management, and regulatory support services to clinical sites entering patients in these trials. Westat is the prime contractor for this project.

The requested nonmaterial/non-substantive change is to approve the addition of the TailorX Data Transmittal Form (DTF). The TailorX DTF was previously approved under the 2010 OMB submission as the PACCT1 DTF, but was not included with the 2013 resubmission because of pending contract issues. There are no substantial changes to the original form and the template follows the Generic DTF template with site identifying information captured in the form header and study-specific case report form schedules in the lower section.

As outlined in Supporting Statements A and B of the OMB package submitted in 2013 for the CTSUS, 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. The use of study-specific DTFs provides a detailed guide for sites as to which forms need to be submitted versus use of the Generic DTF. Please note the addition of the TailorX DTF does not change the overall burden to sites as the development of study-specific DTF is at least partially accounted for under the burden of use estimates provided for the Generic DTF. In addition, since the burden table was submitted in December 2013, the level of burden has decreased for several other CTSU forms due to decreases in the number of respondents. The changes in the number of respondents for specific CTSU forms are outlined below:

- CTSU IRB/Regulatory Approval Transmittal Form (Attachment 1a) - # of respondents decreased from 9,000 to 7297, resulting in a decrease in calculated total annual burden hours.
- CTSU IRB Certification Form (Attachment 1b) - # of respondents decreased from 8500 to 7297, resulting in a decrease in calculated total annual burden hours.
- CTSU Acknowledgement Form (Attachment 1c) - # of respondents decreased from 500 to 125, resulting in a decrease in calculated total annual burden hours.
- MC0845(8233) CTSU Data Transmittal (Attachment 1m) - # of respondents decreased from 50 to 24, resulting in a decrease in calculated total annual burden hours.
- CTSU Patient Enrollment Transmittal Form (Attachment 1o) - # of respondents decreased from 200 to 9, resulting in a decrease in calculated total annual burden hours.

Reductions in the burden for CTSU forms are a result of increased automation, and in the case of the MC0845 Data Transmittal, the closure of the study to further accrual. Even with the addition of the TailorX DTF, the annualized burden hours has decreased from 25,204 hours to 18,270 hours in comparison to the December 2013 estimate. Table 1 shows the updated estimated burden hours. Changes to the burden table are highlighted in yellow.

Summary of Changes

Attachment 1u

Addition of the CTSU Data Transmittal Form for TailorX/PACCT-1. Please note, the fax line and corresponding number were updated to a digital line.

Table 1- February 2015 Level of Burden Estimate for the CTSU Project

Form Name (Attachment #)	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hour
CTSU IRB/Regulatory Approval Transmittal Form (Attachment 1a)	Health Care Practitioner	7,297	9	2/60	2,189
CTSU IRB Certification Form (Attachment 1b)	Health Care Practitioner	7,297	9	10/60	10,946
CTSU Acknowledgement Form (Attachment 1c)	Health Care Practitioner	125	1	5/60	10
Withdrawal from Protocol Participation Form (Attachment 1d)	Health Care Practitioner	50	12	5/60	50
Site Addition (Attachment 1e)	Health Care Practitioner	25	12	5/60	25
CTSU Roster Update Form (Attachment 1f)	Health Care Practitioner	50	12	4/60	40
CTSU Radiation Therapy Facilities Inventory Form (Attachment 1g)	Health Care Practitioner	20	12	30/60	120
CTSU IBCSG Drug Accountability Form (Attachment 1h)	Health Care Practitioner	11	12	10/60	22
CTSU IBCSG Transfer of Investigational Agent Form (Attachment 1i)	Health Care Practitioner	3	12	20/60	12
Site Initiated Data Update Form (Attachment 1j)	Health Care Practitioner	10	12	10/60	20
Data Clarification Form (Attachment 1k)	Health Care Practitioner	341	12	20/60	1,364
RTOG 0834 CTSU Data Transmittal Form (Attachment 1l)	Health Care Practitioner	60	12	10/60	120
MC0845(8233) CTSU Data Transmittal (Attachment 1m)	Health Care Practitioner	24	1	10/60	4
CTSU Generic Data Transmittal Form (Attachment 1n)	Health Care Practitioner	500	12	10/60	1,000
CTSU Patient Enrollment Transmittal Form (Attachment 1o)	Health Care Practitioner	9	1	10/60	2
CTSU P2C Enrollment Transmittal Form (Attachment 1p)	Health Care Practitioner	15	12	10/60	30
CTSU Transfer Form (Attachment 1q)	Health Care Practitioner	20	12	10/60	40

CTSU System Account Request Form (Attachment 1r)	Health Care Practitioner	20	12	20/60	80
CTSU Request for Clinical Brochure (Attachment 1s)	Health Care Practitioner	75	12	10/60	150
CTSU Supply Request Form (Attachment 1t)	Health Care Practitioner	75	12	10/60	150
CTSU Data Transmittal Form for TailorX/PACCT-1 (Attachment 1u)	Health Care Practitioner	567	16	10/60	1,515
CTSU Web Site Customer Satisfaction Survey (Attachment 2)	Health Care Practitioner	275	1	15/60	69
CTSU Helpdesk Customer Satisfaction Survey (Attachment 3)	Health Care Practitioner	325	1	15/60	81
CTSU OPEN Survey (Attachment 4)	Health Care Practitioner	60	1	15/60	15
PIO Customer Satisfaction Survey (Attachment 5)	Health Care Practitioner	100	1	5/60	8
Concept Clinical Trial Survey (Attachment 6)	Health Care Practitioner	500	1	5/60	42
Prospective Clinical Trial Survey (Attachment 7)	Health Care Practitioner	1000	1	5/60	83
Low Accrual Clinical Trial Survey (Attachment 8)	Health Care Practitioner	1000	1	5/60	83
ANNUALIZED TOTALS					18,270