

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request Cancer Trials Support Unit (CTSU) Public Use Forms and Customer Satisfaction Surveys (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 13, 2010 (75 FR 39950) and allowed 60-days for public comment. There have been no public comments. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and

the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title Cancer Trial Support Unit (CTSU). *Type of Information Collection Request:* Existing Collection in Use Without an OMB Number. *Need and Use of Information Collection:* CTSU collects annual surveys of customer satisfaction for clinical site staff using the CTSU Help Desk and the CTSU Web site. An ongoing user satisfaction survey is in place for the Oncology Patient Enrollment Network (OPEN). User satisfaction surveys are compiled as part of the project quality assurance activities and used to direct improvements to processes and technology. In addition, the CTSU collects standardized forms to process site regulatory information, changes to membership, patient enrollment data, and routing information for case report

forms. This questionnaire adheres to The Public Health Service Act, Section 413 (42 U.S.C. 285a-2) authorizes CTEP to establish and support programs to facilitate the participation of qualified investigators on CTEP-supported studies, and to institute programs that minimize redundancy among grant and contract holders, thereby reducing overall cost of maintaining a robust treatment trials program. *Frequency of Response:* The help desk and Web site survey are collected annually. The OPEN survey is ongoing. Submission of forms varies depending on the purpose of the form and the activity of the local site. *Affected Public:* CTSU's target audience is staff members at clinical sites and CTEP-supported programs. Respondent and burden estimates are listed in the Table below. The annualized burden is estimated to be 27,861 hours and the annualized cost to respondents is estimated to be \$757,828. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Attach No.	Section/form or survey title	Use metrics/ month-# respond	Estimated time for site to complete minutes	Estimated burden (minutes/ hours)	Frequency of response	Total annual usage/annual burden hours
1a	CTSU IRB/Regulatory Approval Transmittal Form.	9,000	2	0.03	12.00	3,240
1b	CTSU IRB Certification Form	8,500	10	0.17	12.00	17,340
1c	CTSU Acknowledgement Form	500	5	0.08	12.00	480
1d	Optional Form 1—Withdrawal from Protocol Participation Form.	10	5	0.08	12.00	10
Roster Forms						
1e	CTSU Roster Update Form	50	2-4	0.07	12.00	42
1f	CTSU Radiation Therapy Facilities Inventory Form.	20	30	0.50	12.00	120
Drug Shipment						
1g	CTSU IBCSG Drug Accountability Form	11	5-10	0.17	12.00	22
1h	CTSU IBCSG Transfer of Investigational Agent Form.	3	20	0.33	12.00	12
Data Management						
1i	Site Initiated Data Update Form (generic)	10	5-10	0.17	12.00	20
1j	N0147 CTSU Data Transmittal Form	330	5-10	0.17	12.00	673
1k	Site Initiated Data Update Form (DUF), Protocol: NCCTG N0147*.	30	5-10	0.17	12.00	61
1l	TAILORX/PACCT 1 CTSU Data Transmittal Form.	1200	5-10	0.17	12.00	2,448
1m	Data Clarification Form	144	15-20	0.33	12.00	570
1n	Unsolicited Data Modification Form (UDM), Protocol: TAILORx/PACCT1.	30	5-10	0.17	12.00	61
1o	Z4032 CTSU Data Transmittal Form	58	5-10	0.17	12.00	118
1p	Z1031 CTSU Data Transmittal Form	54	5-10	0.17	12.00	110
1q	Z1041 CTSU Data Transmittal Form	48	5-10	0.17	12.00	98
1r	Z6051 CTSU Data Transmittal Form	12	5-10	0.17	12.00	24
1s	RTOG 0834 CTSU Data Transmittal Form*	60	5-10	0.17	12.00	122
1t	CTSU 7868 Data Transmittal Form	30	5-10	0.17	12.00	61
1u	Site Initiated Data Update Form, Protocol 7868.	10	5-10	0.17	12.00	20
1v	MC0845(8233) CTSU Data Transmittal*	40	5-10	0.17	12.00	82

Attach No.	Section/form or survey title	Use metrics/ month-# respond	Estimated time for site to complete minutes	Estimated burden (minutes/ hours)	Frequency of response	Total annual usage/annual burden hours
1w	8121 CTSU Data Transmittal Form*	40	5-10	0.17	12.00	82
1x	Site Initiated Data Update Form, Protocol 8121.	10	5-10	0.17	12.00	20
1y	USMCI 8214/Z6091: CTSU Data Trans- mittal *In Development.	50	5-10	0.17	12.00	102
1z	USMCI 8214/Z6091 Crossover Request/ Checklist Transmittal Form.	5	5-10	0.17	12.00	10
Patient Enrollment						
1aa	CTSU Patient Enrollment Transmittal Form	600	5-10	0.17	12.00	1,224
1bb	CTSU P2C Enrollment Transmittal Form	30	5-10	0.17	12.00	61
1cc	CTSU Transfer Form	40	5-10	0.17	12.00	82
Administrative						
1dd	CTSU System Account Request Form	10	15-20	0.33	12.00	40
1ee	CTSU Request for Clinical Brochure	35	10	0.17	12.00	71
1ff	CTSU Supply Request Form	130	5-10	0.17	12.00	265
Surveys/Web Forms						
2	CTSU Web Site Customer Satisfaction Sur- vey.	250	10-15	0.2500	1.00	63
3	CTSU Helpdesk Customer Satisfaction Sur- vey.	300	10-15	0.2500	1.00	75
4	CTSU OPEN Survey	120	10-15	0.2500	1.00	30
Annual Totals		21,770	27,861

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at oir_submission@omb.eop.gov or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection

plans and instruments, contact Michael Montello, Pharm. D., CTEP, 6130 Executive Blvd., Rockville, MD 20852. all non-toll-free number 301-435-9206 or e-mail your request, including your address to: montellom@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: September 7, 2010.

Vivian Horovitch-Kelley,
NCI Project Clearance Liaison, National Institutes of Health.

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BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Family-to-Family Health Information Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) will be transferring the Vermont Family-to-Family Health Information Center (F2F

HIC) grant (H84MC00002) from the Parent to Parent (P2P) of Vermont to the Vermont Family Network, Inc. (VFN) in Williston, due to an organizational merger involving these entities and to ensure the continued provision of health resources, financing, related services, and parent-to-parent support for families with children and youth with special health care needs (CYSHCN) in the state of Vermont.

FOR FURTHER INFORMATION CONTACT: LaQuanta Person, Integrated Services Branch, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18A-18, Rockville, MD 20857, via e-mail at lperson@hrsa.gov or call 301.443.2370.

SUPPLEMENTARY INFORMATION:

Former Grantee of Record: Parent to Parent of Vermont.

Original Grant Period: June 1, 2006 to May 31, 2011.

Replacement Awardee: Vermont Family Network, Inc.

Amount of Replacement Award: \$95,700 for the remainder of the project period.

Period of Replacement Award: The period of support for the replacement award is June 1, 2010 to May 31, 2011.

Authority: Section 501(c)(1)(A) of the Social Security Act, as amended.