

Attachment 1: CTSU Standard Forms/Surveys List with Burden and Cost Calculations

Attach No.	Section/Form or Survey Title	Use Metrics/ month - # Respond	Estimated Time for site to complete	Estimated burden (minutes/ hours)	Frequency of Response	Total Annual Usage/Annual Burden Hours	Annual Cost/Item (\$27.20)
Regulatory/Roster							
1a	CTSU IRB/Regulatory Approval Transmittal Form	9,000	2 minutes	0.03	12.00	3,600	97,920.00
1b	CTSU IRB Certification Form	8,500	10 minutes	0.17	12.00	17,000	462,400.00
1c	CTSU Acknowledgement Form	500	5 minutes	0.08	12.00	500	13,600.00
1d	Optional Form 1 - Withdrawal from Protocol Participation Form	50	5 minutes	0.08	12.00	50	1,360.00
Roster Forms							
1e	CTSU Roster Update Form	50	2-4 minutes	0.07	12.00	40	1,088.00
1f	CTSU Radiation Therapy Facilities Inventory Form	20	30 minutes	0.50	12.00	120	3,264.00
Drug shipment							
1g	CTSU IBCSG Drug Accountability Form	11	5-10 minutes	0.17	12.00	22	598.40
1h	CTSU IBCSG Transfer of Investigational Agent Form	3	20 minutes	0.33	12.00	12	326.40
Data Management							
1i	Site Initiated Data Update Form (generic)	100	5-10 minutes	0.17	12.00	200	5,440.00
1j	N0147 CTSU Data Transmittal Form	1000	5-10 minutes	0.17	12.00	2,000	54,400.00
1k	Site Intimated Data Update Form (DUF), Protocol: NCCTG N0147*	75	5-10 minutes	0.17	12.00	150	4,080.00
1l	TAILORX/PACCT 1 CTSU Data Transmittal Form	2100	5-10 minutes	0.17	12.00	4,200	114,240.00
1m	Data Clarification Form	650	15-20 minutes	0.33	12.00	2,600	70,720.00
1n	Unsolicited Data Modification Form (UDM), Protocol:TAILORx/PACCT1	75	5-10 minutes	0.17	12.00	150	4,080.00
1o	Z4032 CTSU Data Transmittal Form	50	5-10 minutes	0.17	12.00	100	2,720.00

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1p	Z1031 CTSU Data Transmittal Form	50	5-10 minutes	0.17	12.00	100	2,720.00
1q	Z1041 CTSU Data Transmittal Form	50	5-10 minutes	0.17	12.00	100	2,720.00
1r	Z6051 CTSU Data Transmittal Form	75	5-10 minutes	0.17	12.00	150	4,080.00
1s	RTOG 0834 CTSU Data Transmittal Form*	60	5-10 minutes	0.17	12.00	120	3,264.00
1t	CTSU 7868 Data Transmittal Form	50	5-10 minutes	0.17	12.00	100	2,720.00
1u	Site Initiated Data Update Form, protocol 7868	10	5-10 minutes	0.17	12.00	20	544.00
1v	MC0845(8233) CTSU Data Transmittal*	50	5-10 minutes	0.17	12.00	100	2,720.00
1w	8121 CTSU Data Transmittal Form*	100	5-10 minutes	0.17	12.00	200	5,440.00
1x	Site Initiated Data Update Form, Protocol 8121	10	5-10 minutes	0.17	12.00	20	544.00
1y	USMCI 8214/Z6091: CTSU Data Transmittal	50	5-10 minutes	0.17	12.00	100	2,720.00
	*In Development						
1z	USMCI 8214/Z6091 Crossover Request/Checklist Transmittal Form	5	5-10 minutes	0.17	12.00	10	272
Patient Enrollment							
1aa	CTSU Patient Enrollment Transmittal Form	600	5-10 minutes	0.17	12.00	1,200	32,640.00
1bb	CTSU P2C Enrollment Transmittal Form	30	5-10 minutes	0.17	12.00	60	1,632.00
1cc	CTSU Transfer Form	40	5-10 minutes	0.17	12.00	80	2,176.00
Administrative							
1dd	CTSU System Account Request Form	50	15-20 minutes	0.33	12.00	200	5,440.00
1ee	CTSU Request for Clinical Brochure	35	10 minutes	0.17	12.00	70	1,904.00

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1ff	CTSU Supply Request Form	130	5-10 minutes	0.17	12.00	260	7,072.00
1gg	CTSU Generic Data Transmittal Form	500	5-10 minutes	0.17	12.00	1000.00	27200.00
Surveys/Web Forms							
2	CTSU Web Site Customer Satisfaction Survey	250	10-15 minutes	0.2500	1.00	63	1,700.00
3	CTSU Helpdesk Customer Satisfaction Survey	300	10-15 minutes	0.2500	1.00	75	2,040.00
4	CTSU OPEN Survey	120	10-15 minutes	0.2500	1.00	30	816.00
Annual Totals		21,770				34,802	946,600.80
Total for 3 year Approval Period						104,404.50	2,839,802.40