



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day comment request

CTEP Support Contracts Forms and Surveys, NCI, NIH

AGENCY: National Institutes of Health.

ACTION: Notice.

In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on December 13, 2016, page 89955 (81FR 89955) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

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

ADDRESSES: 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: Office of Management and Budget, Office of Regulatory Affairs,  
OIRA\_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION: 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., Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, 9609 Medical Center Drive, Rockville, MD 20850 or call non-toll-free number (240-276-6080) or E-mail your request, including your address to: montellom@mail.nih.gov.

PROPOSED COLLECTION: CTEP Support Contracts Forms and Surveys, NCI, 0925-New, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) and the Division of Cancer Prevention (DCP) fund an extensive national program of cancer research, sponsoring clinical trials in cancer prevention, symptom management and treatment for qualified clinical investigators. As part of this effort, CTEP and DCP oversee two support programs, the NCI Central Institutional Review Board (CIRB) and the Cancer Trial Support Unit (CTSU). The purpose of the support programs is to increase efficiency and minimizing burden. The NCI CIRB provides trial oversight satisfying the requirements of 45 CFR 45 and 21 CFR 56 for review of NCI supported studies. The CTSU provides program and systems support for regulatory document collection, membership, data management and patient enrollment. The two programs use integrated systems and processes for managing participant information and documentation of regulatory review.

To meet the responsibilities of each program, information is collected from the sites for purposes of membership, enrollment, opening of IRB approved studies, documenting IRB

review, regulatory approval (for sites not using the CIRB), patient enrollment, and routing of case report forms.

Several surveys are collected to assess satisfaction and provide feedback to guide improvements with processes and technology. Other Surveys have been developed to assess health professional’s interests in clinical trials.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 15,525.

**CTSU and NCI CIRB Forms and CTSU, CIRB and CTEP Surveys – Estimated Annualized Burden Hours**

<b>Form Name</b>	<b>Type of Respondent</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden Per Response (in hours)</b>	<b>Total Annual Burden Hours</b>
CTSU IRB/Regulatory Approval Transmittal Form (Attachment A1)	Health Care Practitioner	2444	12	2/60	978
CTSU IRB Certification Form (Attachment A2)	Health Care Practitioner	2444	12	10/60	4,888
Withdrawal from Protocol Participation Form (Attachment A3)	Health Care Practitioner	279	1	10/60	47
Site Addition Form (Attachment A4)	Health Care Practitioner	80	12	10/60	160
CTSU Roster Update Form (Attachment A5)	Health Care Practitioner	600	1	5/60	50
CTSU Request for Clinical Brochure (Attachment A6)	Health Care Practitioner	360	1	10/60	60

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CTSU Supply Request Form (Attachment A7)	Health Care Practitioner	90	12	10/60	180
Site Initiated Data Update Form (Attachment A8)	Health Care Practitioner	2	12	10/60	4
Data Clarification Form (Attachment A9)	Health Care Practitioner	150	24	10/60	600
RTOG 0834 CTSU Data Transmittal Form (Attachment A10)	Health Care Practitioner	12	76	10/60	152
MC0845(8233) CTSU Data Transmittal (Attachment A11)	Health Care Practitioner	5	12	10/60	10
CTSU Generic Data Transmittal Form (Attachment A12)	Health Care Practitioner	5	12	10/60	10
TAILORx_PACCT1_Data Transmittal Form (Attachment A13)	Health Care Practitioner	161	96	10/60	2576
Unsolicited Data Modification Form: Protocol: TAILORx/PACCT-1 (Attachment 14)	Health Care Practitioner	30	12	10/60	60
CTSU Patient Enrollment Transmittal Form (Attachment A15)	Health Care Practitioner	12	12	10/60	24
CTSU Transfer Form (Attachment A16)	Health Care Practitioner	360	2	10/60	120

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CTSU System Access Request Form (Attachment A17)	Health Care Practitioner	180	1	20/60	60
NCI CIRB AA & DOR between the NCI CIRB and Signatory Institution (Attachment B1)	Participants	50	1	15/60	13
NCI CIRB Signatory Enrollment Form (Attachment B2)	Participants	50	1	15/60	13
CIRB Board Member Biographical Sketch Form (Attachment B3)	Board Member	25	1	15/60	6
CIRB Board Member Contact Information Form (Attachment B4)	Board Member	25	1	10/60	4
CIRB Board Member NDA (Attachment B6)	Board Member	25	1	10/60	4
CIRB Direct Deposit Form (Attachment B7)	Board Member	25	1	15/60	6
CIRB Member COI Screening Worksheet (Attachment B8)	Board Members	12	1	30/60	6
CIRB COI Screening for CIRB meetings (Attachment B9)	Board Members	72	1	15/60	18

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CIRB IR Application (Attachment B10)	Health Care Practitioner	80	1	1	80
CIRB IR Application for Exempt Studies (Attachment B11)	Health Care Practitioner	4	1	30/60	2
CIRB Amendment Review Application (Attachment B12)	Health Care Practitioner	400	1	15/60	100
CIRB Ancillary Studies Application (Attachment B13)	Health Care Practitioner	1	1	1	1
CIRB Continuing Review Application (Attachment B14)	Health Care Practitioner	400	1	30/60	200
Adult IR of Cooperative Group Protocol (Attachment B15)	Board Members	65	1	180/60	195
Pediatric IR of Cooperative Group Protocol (Attachment B16)	Board Members	15	1	180/60	45
Adult Continuing Review of Cooperative Group Protocol (Attachment B17) Protocol	Board Members	275	1	1	275

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Pediatric Continuing Review of Cooperative Group Protocol (Attachment B18)	Board Members	130	1	1	130
Adult Amendment of Cooperative Group Protocol (Attachment B19)	Board Members	40	1	120/60	80
Pediatric Amendment of Cooperative Group Protocol (Attachment B20)	Board Members	25	1	120/60	50
Pharmacist's Review of a Cooperative Group Study (Attachment B21)	Board Members	10	1	120/60	20
CPC Pharmacist's Review of Cooperative Group Study (Attachment B22)	Board Members	20	1	120/60	40
Adult Expedited Amendment Review (Attachment B23)	Board Members	348	1	30/60	174
Pediatric Expedited Amendment Review (Attachment B24)	Board Members	140	1	30/60	70

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Adult Expedited Continuing Review (Attachment B25)	Board Members	140	1	30/60	70
Pediatric Expedited Continuing Review (Attachment B26)	Board Members	36	1	30/60	18
Adult Cooperative Group Response to CIRB Review (Attachment B27)	Health Care Practitioner	30	1	1	30
Pediatric Cooperative Group Response to CIRB Review (Attachment B28)	Health Care Practitioner	5	1	1	5
Adult Expedited Study Chair Response to Required Mod (Attachment B29)	Board Members	40	1	15/60	10
Pediatric Expedited Study Chair Response to Required Mod (Attachment B30)	Board Members	40	1	15/60	10
Reviewer Worksheet - Determination of UP or SCN (Attachment B31)	Board Members	360	1	10/60	61

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Reviewer Worksheet -CIRB Statistical Reviewer Form (Attachment B32)	Board Members	100	1	1	100
CIRB Application for Translated Documents (Attachment B33)	Health Care Practitioner	100	1	30/60	50
Reviewer Worksheet of Translated Documents (Attachment B34)	Board Members	100	1	15/60	25
Reviewer Worksheet of Recruitment Material (Attachment B35)	Board Members	20	1	15/60	5
Reviewer Worksheet Expedited Study Closure Review (Attachment B36)	Board Members	20	1	15/60	5
Reviewer Worksheet Expedited Review of Study Chair Response to CIRB-Required Modifications (Attachment B37)	Board Members	5	1	30/60	3
Reviewer Worksheet of Expedited IR (Attachment B38)	Board Members	5	1	30/60	3

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Reviewer Worksheet -CPC - Determination of UP or SCN (Attachment B39)	Board Members	40	1	15/60	10
Annual Signatory Institution Worksheet About Local Context (Attachment B40)	Health Care Practitioner	400	1	40/60	267
Annual Principal Investigator Worksheet About Local Context (Attachment B41)	Health Care Practitioner	1800	1	20/60	600
Study-Specific Worksheet About Local Context (Attachment B42)	Health Care Practitioner	4800	1	20/60	1600
Study Closure or Transfer of Study Review Responsibility Form (Attachment B43)	Health Care Practitioner	1680	1	15/60	420
UP or SCN Reporting Form (Attachment B44)	Health Care Practitioner	360	1	20/60	120
Change of SI PI Form (Attachment B45)	Health Care Practitioner	120	1	15/60	30
CTSU Website Customer Satisfaction Survey (Attachment C1)	Health Care Practitioner	275	1	15/60	69

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CTSU Help Desk Customer Satisfaction Survey (Attachment C2)	Health Care Practitioner	325	1	15/60	81
CTSU OPEN Survey (Attachment C3)	Health Care Practitioner	60	1	15/60	15
CIRB Customer Satisfaction Survey (Attachment C4) Satisfaction Survey (Attachment C4)	Participants	600	1	15/60	150
Follow-up Survey (Communication Audit) (Attachment C5)	Participants/ Board Members	300	1	15/60	75
Website Focus Groups, Communication Project (Attachment C6 A-D)	Participants/ Board Members	18	1	1	18
CIRB Board Member Annual Assessment Survey (Attachment C7)	Board Members	60	1	20/60	20
PIO Customer Satisfaction Survey (Attachment C8)	Health Care Practitioner	60	1	5/60	5
Concept Clinical Trial Survey (Attachment C9)	Health Care Practitioner	500	1	5/60	42

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Prospective Clinical Trial Survey (Attachment C10)	Health Care Practitioner	1000	1	1/60	17
Low Accrual Clinical Trial Survey (Attachment C11)	Health Care Practitioner	1000	1	1/60	17
ETCTN PI Survey (Attachment 12)	Physician	75	1	15/60	19
ETCTN RS Survey (Attachment 13)	Health Care Practitioner	175	1	15/60	44
<b>Totals</b>		<b>24,100</b>	<b>100,337</b>		<b>15,525</b>

Dated: February 15, 2017

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Office of Management Policy and Compliance  
National Cancer Institute (NCI) National Institutes of Health (NIH)  
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