

proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Karla Bailey, Office of Management Policy and Compliance, National Cancer Institute, 9609 Medical Center Drive, Bethesda, MD 20892-9760 or call non-toll-free number (240) 276-5582 or Email your request, including your address to: [karla.bailey@nih.gov](mailto:karla.bailey@nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** Section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) 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) 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to 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.

*Proposed Collection Title:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NCI), 0925-0642, Revision,

National Cancer Institute (NCI), National Institutes of Health (NIH).

*Need and Use of Information Collection:* This information collection activity is collecting qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. This generic provides information about the National Cancer Institute's customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. It also allows feedback to contribute directly to the improvement of program management. Feedback collected under this generic clearance provides useful information but it will not yield data that can be generalized to the overall population.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated burden hours are 8,917.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of collection	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Surveys .....	10,000	1	30/60	5,000
In-Depth Interviews (IDIs) or Small Discussion Groups .....	500	1	90/60	750
Focus Groups .....	1,000	1	90/60	1,500
Website or Software Usability Tests .....	5,000	1	20/60	1,667
<b>Total .....</b>	<b>16,500</b>	<b>16,500</b>	<b>.....</b>	<b>8,917</b>

Dated: December 7, 2016.

**Karla Bailey,**

*Project Clearance Liaison, National Cancer Institute, National Institutes of Health.*

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**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; 60-Day Comment Request; CTEP Support Contracts Forms and Surveys (National Cancer Institute)**

**AGENCY:** National Institutes of Health, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork

Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Michael Montello, Pharm. D., Cancer Therapy Evaluation Program (CTEP), 9609 Medical Center Drive, MSC 9742, Rockville, MD 20850 or call non-toll-free number 240-276-6080 or Email your request, including your

address to: [montellom@mail.nih.gov](mailto:montellom@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) 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) 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to 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.

*Proposed Collection Title:* CTEP Support Contracts Forms and Surveys, 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 (CTSUSU). 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 CTSUSU 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 15,531.

## ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
CTSUSU IRB/Regulatory Approval Transmittal Form	Health Care Practitioner	2,444	12	2/60	978
CTSUSU IRB Certification Form	Health Care Practitioner	2,444	12	10/60	4,888
Withdrawal from Protocol Participation Form	Health Care Practitioner	279	1	10/60	47
Site Addition Form	Health Care Practitioner	80	12	10/60	160
CTSUSU Roster Update Form	Health Care Practitioner	600	1	5/60	50
CTSUSU Request for Clinical Brochure	Health Care Practitioner	360	1	10/60	60
CTSUSU Supply Request Form	Health Care Practitioner	90	12	10/60	180
Site Initiated Data Update Form	Health Care Practitioner	2	12	10/60	4
Data Clarification Form	Health Care Practitioner	150	24	10/60	600
RTOG 0834 CTSUSU Data Transmittal Form	Health Care Practitioner	12	76	10/60	152
MC0845(8233) CTSUSU Data Transmittal	Health Care Practitioner	5	12	10/60	10
CTSUSU Generic Data Transmittal Form	Health Care Practitioner	5	12	10/60	10
TAILORx_PACCT1 Data Transmittal Form	Health Care Practitioner	161	96	10/60	2,576
Unsolicited Data Modification Form: Protocol: TAILORx/PACCT-1.	Health Care Practitioner	30	12	10/60	60
CTSUSU Patient Enrollment Transmittal Form	Health Care Practitioner	12	12	10/60	24
CTSUSU Transfer Form	Health Care Practitioner	360	2	10/60	120
CTSUSU System Access Request Form	Health Care Practitioner	180	1	20/60	60
NCI CIRB AA & DOR between the NCI CIRB and Signatory Institution.	Participants	50	1	15/60	13
NCI CIRB Signatory Enrollment Form	Participants	50	1	15/60	13
CIRB Board Member Biographical Sketch Form	Board Member	25	1	15/60	6
CIRB Board Member Contact Information Form	Board Member	25	1	10/60	4
CIRB Board Member W-9	Board Member	25	1	15/60	6
CIRB Board Member NDA	Board Member	25	1	10/60	4
CIRB Direct Deposit Form	Board Member	25	1	15/60	6
CIRB Member COI Screening Worksheet	Board Members	12	1	30/60	6
CIRB COI Screening for CIRB meetings	Board Members	72	1	15/60	18
CIRB IR Application	Health Care Practitioner	80	1	60/60	80
CIRB IR Application for Exempt Studies	Health Care Practitioner	4	1	30/60	2
CIRB Amendment Review Application	Health Care Practitioner	400	1	15/60	100
CIRB Ancillary Studies Application	Health Care Practitioner	1	1	60/60	1
CIRB Continuing Review Application	Health Care Practitioner	400	1	30/60	200
Adult IR of Cooperative Group Protocol	Board Members	65	1	180/60	195
Pediatric IR of Cooperative Group Protocol	Board Members	15	1	180/60	45
Adult Continuing Review of Cooperative Group Protocol.	Board Members	275	1	60/60	275
Pediatric Continuing Review of Cooperative Group Protocol.	Board Members	130	1	60/60	130
Adult Amendment of Cooperative Group Protocol	Board Members	40	1	120/60	80
Pediatric Amendment of Cooperative Group Protocol.	Board Members	25	1	120/60	50
Pharmacist's Review of a Cooperative Group Study.	Board Members	10	1	120/60	20
CPC Pharmacist's Review of Cooperative Group Study.	Board Members	20	1	120/60	40
Adult Expedited Amendment Review	Board Members	348	1	30/60	174

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Pediatric Expedited Amendment Review .....	Board Members .....	140	1	30/60	70
Adult Expedited Continuing Review .....	Board Members .....	140	1	30/60	70
Pediatric Expedited Continuing Review .....	Board Members .....	36	1	30/60	18
Adult Cooperative Group Response to CIRB Review.	Health Care Practitioner	30	1	60/60	30
Pediatric Cooperative Group Response to CIRB Review.	Health Care Practitioner	5	1	60/60	5
Adult Expedited Study Chair Response to Required Mod.	Board Members .....	40	1	15/60	10
Pediatric Expedited Study Chair Response to Required Mod.	Board Members .....	40	1	15/60	10
Reviewer Worksheet—Determination of UP or SCN.	Board Members .....	360	1	10/60	61
Reviewer Worksheet—CIRB Statistical Reviewer Form.	Board Members .....	100	1	60/60	100
CIRB Application for Translated Documents .....	Health Care Practitioner	100	1	30/60	50
Reviewer Worksheet of Translated Documents ...	Board Members .....	100	1	15/60	25
Reviewer Worksheet of Recruitment Material .....	Board Members .....	20	1	15/60	5
Reviewer Worksheet Expedited Study Closure Review.	Board Members .....	20	1	15/60	5
Reviewer Worksheet Expedited Review of Study Chair Response to CIRB—Required Modifications.	Board Members .....	5	1	30/60	3
Reviewer Worksheet of Expedited IR .....	Board Members .....	5	1	30/60	3
Reviewer Worksheet—CPC—Determination of UP or SCN.	Board Members .....	40	1	15/60	10
Annual Signatory Institution Worksheet About Local Context.	Health Care Practitioner	400	1	40/60	267
Annual Principal Investigator Worksheet About Local Context.	Health Care Practitioner	1,800	1	20/60	600
Study-Specific Worksheet About Local Context ...	Health Care Practitioner	4,800	1	20/60	1,600
Study Closure or Transfer of Study Review Responsibility Form.	Health Care Practitioner	1,680	1	15/60	420
UP or SCN Reporting Form .....	Health Care Practitioner	360	1	20/60	120
Change of SI PI Form .....	Health Care Practitioner	120	1	15/60	30
CTSU Web site Customer Satisfaction Survey ...	Health Care Practitioner	275	1	15/60	69
CTSU Help Desk Customer Satisfaction Survey	Health Care Practitioner	325	1	15/60	81
CTSU OPEN Survey .....	Health Care Practitioner	60	1	15/60	15
CIRB Customer Satisfaction Survey .....	Participants .....	600	1	15/60	150
Follow-up Survey (Communication Audit) .....	Participants/Board Members.	300	1	15/60	75
Web site Focus Groups, Communication Project	Participants/Board Members.	18	1	60/60	18
CIRB Board Member Annual Assessment Survey	Board Members .....	60	1	20/60	20
PIO Customer Satisfaction Survey .....	Health Care Practitioner	60	1	5/60	5
Concept Clinical Trial Survey .....	Health Care Practitioner	500	1	5/60	42
Prospective Clinical Trial Survey .....	Health Care Practitioner	1,000	1	1/60	17
Low Accrual Clinical Trial Survey .....	Health Care Practitioner	1,000	1	1/60	17
ETCTN PI Survey .....	Physician .....	75	1	15/60	19
ETCTN RS Survey .....	Health Care Practitioner	175	1	15/60	44
Totals .....	.....	24,125	100,362	.....	15,531

Dated: December 1, 2016.

Karla Bailey,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

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**DEPARTMENT OF HOMELAND SECURITY****Office of the Secretary****[Docket No. DHS–2016–0088]****Privacy Act of 1974; Department of Homeland Security/U.S. Customs and Border Protection-007 Border Crossing Information (BCI) System of Records****AGENCY:** Department of Homeland Security, Privacy Office.**ACTION:** Notice of Privacy Act System of Records.**SUMMARY:** In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to update and reissue a current Department of Homeland Security system of records titled, “Department of Homeland Security (DHS)/U.S. Customs and Border Protection (CBP)-007 Border Crossing Information (BCI) System of Records.” This system of records allows