



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Cancer Therapy Evaluation Program (CTEP) Branch and Support Contracts Forms and Surveys (NCI)

AGENCY: National Institutes of Health, HHS.

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 proposed 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, Cancer Therapy Evaluation Program - DCTD, National Cancer Institute, 9609 Medical Center Drive, Rockville, Maryland, 20850 or call non-toll-free number (240) 276-6080 or e-mail your request, including your address to: 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: Cancer Therapy Evaluation Program (CTEP) Branch and Support Contracts Forms and Surveys (NCI), 0925-0753, Expiration Date 03/31/2026, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a request for OMB to approve the revised information collection, Cancer Therapy Evaluation Program (CTEP) Support Contracts Forms and Survey. It includes modifications to OMB-approved forms for the CTSU and CIRB and the addition of new forms for the CTSU, CIRB, and CTEP. The National Cancer Institute (NCI) 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 implements programs to register clinical site investigators and clinical site staff and to oversee the conduct of research at the clinical sites. CTEP and DCP also oversee two support programs, the NCI Central Institutional Review Board (CIRB) and the Cancer Trial Support Unit (CTSU). The combined systems and processes for initiating and managing clinical trials are termed the Clinical Oncology Research Enterprise (CORE) and represent an integrated set of information systems and processes that support investigator registration, trial oversight, patient enrollment, and clinical data collection. The information collected is required to ensure compliance with applicable federal regulations governing the conduct of human subjects' research (45 CFR 46 and 21 CFR 50), and when CTEP acts as the Investigational New Drug (IND) holder (Food and Drug Administration (FDA) regulations pertaining to the sponsor of clinical trials and the selection of qualified investigators under 21 CFR 312.53).

Survey collections assess satisfaction and provide feedback to guide improvements with processes and technology.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 162,831 hours.

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
CTSU IRB/Regulatory Approval Transmittal Form (Attachment A01)	Health Care Practitioner	2444	12	2/60	978
CTSU IRB Certification Form (Attachment A02)	Health Care Practitioner	2444	12	10/60	4888
Withdrawal from Protocol Participation Form (Attachment A03)	Health Care Practitioner	279	1	10/60	47
Site Addition Form (Attachment A04)	Health Care Practitioner	80	12	10/60	160
CTSU Request for Clinical Brochure (Attachment A06)	Health Care Practitioner	360	1	10/60	60
CTSU Supply Request Form (Attachment A07)	Health Care Practitioner	90	12	10/60	180
RTOG 0834 CTSU Data Transmittal Form (Attachment A10)	Health Care Practitioner	30	2	5/60	5
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
CTSU OPEN Rave Request Form (Attachment A18)	Health Care Practitioner	30	21	10/60	105
CTSU LPO Form Creation (Attachment A19)	Health Care Practitioner	5	2	120/60	20
CTSU Site Form Creation and PDF (Attachment A20)	Health Care Practitioner	400	10	30/60	2000
CTSU PDF Signature Form (Attachment A21)	Health Care Practitioner	400	10	10/60	667

CTSU CLASS Course Setup Request Form (Attachment A22)	Health Care Practitioner	10	2	20/60	7
CTSU LPO Approval of Early Closure Form (Attachment A23)	Health Care Practitioner	2444	6	20/60	4888
International DTL Signing (Attachment 24)	Health Care Practitioner	29	1	10/60	5
NCI CIRB AA & DOR between the NCI CIRB and Signatory Institution (Attachment B01)	Participants	50	1	15/60	13
NCI CIRB Signatory Enrollment Form (Attachment B02)	Participants	50	1	15/60	13
CIRB Board Member Application (Attachment B03)	Board Member	100	1	30/60	50
CIRB Member COI Screening Worksheet (Attachment B08)	Board Members	100	1	15/60	25
CIRB COI Screening for CIRB meetings (Attachment B09)	Board Members	72	1	15/60	18
CIRB IR Application (Attachment B10)	Health Care Practitioner	80	1	60/60	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	60/60	1
CIRB Continuing Review Application (Attachment B14)	Health Care Practitioner	400	1	15/60	100
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	Board Members	275	1	60/60	275

(Attachment B17) Protocol					
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	50	1	120/60	100
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
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	60/60	30
Pediatric Cooperative Group Response to CIRB Review (Attachment B28)	Health Care Practitioner	5	1	60/60	5
Adult Expedited Study Chair Response to Required Modifications (Attachment B29)	Board Members	40	1	30/60	20
Reviewer Worksheet- Determination of UP or SCN (Attachment B31)	Board Members	400	1	10/60	67
Reviewer Worksheet -CIRB Statistical Reviewer Form (Attachment B32)	Board Members	100	1	15/60	25
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 of Expedited IR (Attachment B38)	Board Members	5	1	30/60	3
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	15/60	1200
Study Closure or Transfer of Study Review Responsibility (Attachment B43)	Health Care Practitioner	1680	1	15/60	420
Unanticipated Problem or Serious or Continuing Noncompliance Reporting Form (Attachment B44)	Health Care Practitioner	360	1	20/60	120
Change of Signatory Institution PI Form (Attachment B45)	Health Care Practitioner	120	1	20/60	40
Request Waiver of Assent Form (Attachment B46)	Health Care Practitioner	35	1	20/60	12
CIRB Waiver of Consent Request Supplemental Form (Attachment B47)	Health Care Practitioner	20	1	15/60	5
Review Worksheet CIRB Review for Inclusion of Incarcerated Participants (Attachment B48)	Board Members	20	1	60/60	20

Notification of Incarcerated Participant Form (Attachment B49)	Health Care Practitioner	20	1	20/60	7
Final Video Submission Posting Form (Attachment B50)	Health Care Practitioner	80	1	15/60	20
Unanticipated Problem or Serious or Continuing Noncompliance Application (Attachment B52)	Health Care Practitioner	20	1	30/60	10
CIRB Customer Satisfaction Survey (Attachment C04)	Participants	600	1	15/60	150
Follow-up Survey (Communication Audit) (Attachment C05)	Participants/ Board Members	300	1	15/60	75
CIRB Board Member Annual Assessment Survey (Attachment C07)	Board Members	60	1	15/60	15
Audit Scheduling Form (Attachment D01)	Health Care Practitioner	229	5	21/60	401
Preliminary Audit Finding Form (Attachment D02)	Health Care Practitioner	229	5	10/60	191
Audit Maintenance Form (Attachment D03)	Health Care Practitioner	158	5	9/60	119
Final Audit finding Report Form (Attachment D04)	Health Care Practitioner	110	11	1098/60	22143
Follow-up Form (Attachment D05)	Health Care Practitioner	44	7	27/60	139
Roster Maintenance Form (Attachment D06)	Health Care Practitioner	7	1	18/60	2
Final Report and CAPA Request Form (Attachment D07)	Health Care Practitioner	3	9	1800/60	810
NCI/DCTD/CTEP FDA Form 1572 for Annual Submission (Attachment E01)	Physician	26,500	1	15/60	6625
NCI/DCTD/CTE Biosketch (Attachment E02)	Physician; Health Care PR actioner	48,000	1	120/60	96000
NCI/DCTD/CTEP Financial Disclosure Form (Attachment E03)	Physician; Health Care PR actioner	48,000	1	15/60	12000

NCI/DCTD/CTEP Agent Shipment Form (ASF) (Attachment E04)	Physician	24,000	1	10/60	4000
NINT Registration Form?	Health Care Practitioner, Other	1,000	1	60/60	1000
ISS Form	Physician	2,100	1	15/60	525
Basic Study Information Form (Attachment TBD)	Health Care PR actioner	140	1	20/60	47
Totals		173,463	253,510		162,831

Dated: November 8, 2023.

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