



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Submission for OMB Review; 30-Day Comment Request; Cancer Therapy Evaluation Program (CTEP) Branch and Support Contracts Forms and Surveys (NCI); Correction**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

**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.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or using the search function.

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

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the **Federal Register** on March 8, 2024, page 16776 (89 FR 16776)

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. The National Cancer Institute (NCI), 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.

In compliance with section 3507(a)(1)(D) of 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.

*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 CFF 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 162,836 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                       |

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|---|--------------------------|------|----|--------|------|
| 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  |

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| 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 | 60/60  | 275 |
| 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  | Board Members            | 400 | 1 | 10/60  | 67  |

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| or SCN (Attachment B31)  |                          |      |   |       |      |
| 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   |

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| 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/<br>Board Members | 300 | 1  | 15/60   | 75    |
| CIRB Board Member Annual Assessment Survey (Attachment C07)                               | Board Members                  | 60  | 1  | 15/60   | 15    |
| PIO Customer Satisfaction Survey (Attachment C08)   | Health Care Practitioner       | 60  | 1  | 5/60    | 5     |
| 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   |

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| 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             |
| <b>Totals</b>  |                                    | <b>173,523</b> | <b>253,570</b> |        | <b>162,836</b> |

Dated: March 20, 2024.

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