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Dated: February 9, 2021.

**Miguelina Perez,**

Program Analyst, Office of Federal Advisory Committee Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; 30-Day Comment Request; CTEP Branch and Support Contracts Forms and Surveys (National Cancer Institute)

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

**ACTION:** Notice.

**SUMMARY:** 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.

**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 recommendations for the proposed information collection should be sent within 30 days of publication of this

notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

#### FOR FURTHER INFORMATION 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).

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the **Federal Register** on October 8, 2020, page 63565 (Vol. 85, No. 196, FR 63565) and allowed 60 days for public comment. No public comments were received. 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:* CTEP Support Contract Forms and Surveys (NCI), OMB #0925-0753 Expiration Date 07/31/2021, REVISION, 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 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 is termed the Clinical Oncology Research Enterprise (CORE) and represents an integrated set of information systems and processes which 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, 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 151,792.

### 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	2,444	12	2/60	978
CTSU IRB Certification Form (Attachment A02) ..	Health Care Practitioner	2,444	12	10/60	4,888
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	12	76	10/60	152
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 System Access Request Form (Attachment A17).	Health Care Practitioner	180	1	10/60	30
CTSU OPEN Rave Request Form (Attachment A18).	Health Care Practitioner	30	21	10/60	105

## 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
CTSU LPO Form Creation (Attachment A19) .....	Health Care Practitioner	5	2	120/60	20
CTSU Site Form Creation (Attachment A20) .....	Health Care Practitioner	400	10	30/60	2,000
CTSU Electronic Signature Form (Attachment A21).	Health Care Practitioner	400	10	10/60	667
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 (Attachment B17).	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 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	1,800	1	20/60	600
Study-Specific Worksheet About Local Context (Attachment B42).	Health Care Practitioner	4,800	1	15/60	1,200

## 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
Study Closure or Transfer of Study Review Responsibility (Attachment B43).	Health Care Practitioner	1,680	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 (B49).	Health Care Practitioner	20	1	20/60	7
CTSU OPEN Survey (Attachment C03) .....	Health Care Practitioner	10	1	15/60	3
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
PIO Customer Satisfaction Survey (Attachment C08).	Health Care Practitioner	60	1	5/60	5
Audit Scheduling Form (Attachment D01) .....	Health Care Practitioner	152	5	21/60	266
Preliminary Audit Finding Form (Attachment D02)	Health Care Practitioner	152	5	10/60	127
Audit Maintenance Form (Attachment D03) .....	Health Care Practitioner	152	5	9/60	114
Final Audit finding Report Form (Attachment D04).	Health Care Practitioner	75	11	1,098/60	15,098
Follow-up Form (Attachment D05) .....	Health Care Practitioner	75	7	27/60	236
Roster Maintenance Form (Attachment D06) .....	Health Care Practitioner	5	1	18/60	2
Final Report and CAPA Request Form (Attachment D07).	Health Care Practitioner	12	9	1,800/60	3,240
NCI/DCTD/CTEP FDA Form 1572 for Annual Submission (Attachment E01).	Physician .....	26,500	1	15/60	6,625
NCI/DCTD/CTE Biosketch (Attachment E02) .....	Physician; Health Care Practitioner.	48,000	1	120/60	96,000
NCI/DCTD/CTEP Financial Disclosure Form (Attachment E03).	Physician; Health Care Practitioner.	48,000	1	15/60	12,000
NCI/DCTD/CTEP Agent Shipment Form (ASF) (Attachment E04).	Physician .....	24,000	1	10/60	4,000
Totals .....	.....	167,715	235,670	.....	151,792

Dated: February 1, 2021.

**Diane Kreinbrink,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention's (CSAP) Drug Testing Advisory Board

(DTAB) will convene via web conference on March 2nd, 2021, from 10:00 a.m. EST to 4:30 p.m. EST, and March 3rd, 2021, from 10:00 a.m. EST to 4:30 p.m. EST.

The board will meet in open-session March 2nd, 2021, from 10:00 a.m. EST to 2:00 p.m. EST to discuss the Mandatory Guidelines for Federal Workplace Drug Testing Programs with updates from the Department of Transportation, the Nuclear Regulatory Commission, and the Department of Defense. Other discussion topics include an update on marijuana studies and efforts as well as the Employee Assistance Program (EAP) Toolkit. The board will meet in closed-session on March 2nd, 2021, from 2:15 p.m. EST to 4:30 p.m. EST, and March 3rd, 2021, from 10:00 a.m. EST to 4:30 p.m. EST,

to discuss confidential issues surrounding the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs (hair), the Federal Drug-Free Workplace Programs and emerging issues, updates on the revisions of the Urine and Oral Fluid Mandatory Guidelines and the Biomarker Table, preliminary and unpublished studies from the Johns Hopkins University Behavioral Pharmacology Research Unit (BPRU), and cannabidiol (CBD) information from FDA. Therefore, the March 2nd, 2021, from 2:15 p.m. EST to 4:30 p.m. EST, and the March 3rd, 2021, from 10:00 a.m. EST to 4:30 p.m. EST, meetings are closed to the public, as determined by the Assistant Secretary for Mental Health and Substance Use, SAMHSA, in accordance with 5 U.S.C. 552b(c)(4) and