

amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-22-233: Time-Sensitive Opportunities for Health Research.

*Date:* December 8, 2023.

*Time:* 11:00 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Wenjuan Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 480-8667, wangw22@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 8, 2023.

**Patricia B. Hansberger,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2023-25072 Filed 11-13-23; 8:45 am]

**BILLING CODE 4140-01-P**

## 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 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:* 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

## 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
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 (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 or SCN (Attachment B31).	Board Members .....	400	1	10/60	67

## 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
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/ .....	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 Practitioner.	48,000	1	120/60	96000
NCI/DCTD/CTEP Financial Disclosure Form (Attachment E03).	Physician; Health Care Practitioner.	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 Practitioner	140	1	20/60	47
Totals .....	.....	173,463	253,510	.....	162,831

Dated: November 8, 2023.

**Diane Kreinbrink,**

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

[FR Doc. 2023-25022 Filed 11-13-23; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Cancer Institute; Notice of Closed Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to internal NCI committees that will decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; OCT2023 Cycle 45 NExT SEP Committee Meeting.

*Date:* December 12, 2023.

*Time:* 10:00 a.m. to 2:00 p.m.

*Agenda:* To evaluate the NCI Experimental Therapeutics Program Portfolio.

*Place:* National Institutes of Health, 9000 Rockville Pike, Building 31, Room 3A44, Bethesda, Maryland 20892 (Virtual Meeting).

*Contact Persons:* Barbara Mroczkowski, Ph.D., Executive Secretary, Discovery Experimental Therapeutics Program, National Cancer Institute, NIH, 31 Center Drive, Room 3A44, Bethesda, Maryland

20892, 301-496-4291, [mroczkoskib@mail.nih.gov](mailto:mroczkoskib@mail.nih.gov).

Toby Hecht, Ph.D., Executive Secretary, Development Experimental Therapeutics Program, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 3W110, Rockville, Maryland 20850, 240-276-5683, [toby.hecht2@nih.gov](mailto:toby.hecht2@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 8, 2023.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2023-25069 Filed 11-13-23; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

[Docket No. USCG-2010-1066]

**Recreational Boating Safety Projects, Programs, and Activities Funded Under Provisions of the Infrastructure Investment and Jobs Act; Fiscal Year 2023**

**ACTION:** Notice.

**SUMMARY:** The Coast Guard is publishing this notice to satisfy a requirement of the Infrastructure Investment and Jobs Act that requires a detailed accounting of the projects, programs, and activities funded under the national recreational boating safety program provision of the Act be published annually in the **Federal Register**. This notice specifies the funding amounts the Coast Guard has committed, obligated, or expended during fiscal year 2023, as of September 30, 2023.

**FOR FURTHER INFORMATION CONTACT:** For questions on this notice please contact Mr. Jeff Decker, U.S. Coast Guard, Regulations Development Manager, (202) 372-1507 or <mailto:RBSInfo@uscg.mil>.

**SUPPLEMENTARY INFORMATION:**

**Background and Purpose**

Since 1998, Congress has passed a series of laws providing funding for projects, programs, and activities funded under the national recreational boating safety program, which is administered by the U.S. Coast Guard. On November 15, 2021, the Infrastructure Investment and Jobs Act (Pub. L. 117-58, Sec. 28001) set aside funding for Coast Guard administration, which for fiscal year 2023 was \$13.835 million. Of that, not less than \$2.1 million shall be made available to ensure compliance with chapter 43 of title 46, U.S. Code, and not more than \$1.5 million is available to conduct by grant or contract a survey of levels of recreational boating participation and related matters in the United States.

These funds are available to the Secretary from the Sport Fish Restoration and Boating Trust Fund (Trust Fund) established under 26 U.S.C. 9504(a) for payment of Coast Guard expenses for personnel and activities directly related to coordinating and carrying out the national recreational boating safety program. Amounts made available under this subsection remain available during the two succeeding fiscal years. Any amount that is unexpended or unobligated at the end of the three-year period during which it is available shall be withdrawn by the Secretary and allocated to the States in addition to any other amounts available for allocation in the fiscal year in which they are withdrawn or the following fiscal year.

Use of these funds requires compliance with standard Federal contracting rules with associated lead and processing times resulting in a lag time between available funds and spending. The total amount of funding transferred to the Coast Guard from the Trust Fund, and committed, obligated, and/or expended during fiscal year 2023 for each project is shown below.

**Specific Accounting of Funds**

The total amount of funding transferred to the Coast Guard from the Sport Fish Restoration and Boating Trust Fund and committed, obligated, and/or expended during fiscal year 2023 for each project is shown in the chart below.

Project	Description	Cost
46 U.S.C. 43 Compliance: Inspection Program/Boat Testing Program.	Provided for continuance of the national recreational boat compliance inspection program, which began in January 2001.	\$2,484,350
46 U.S.C. 43 Compliance: Staff Salaries .....	Provided for 3 personnel to oversee manufacturer compliance with 46 U.S.C. 43 requirements.	558,743
46 U.S.C. 43 Compliance: Staff Travel .....	Provided for travel by employees of the Boating Safety Division to oversee manufacturer compliance with 46 U.S.C. 43 requirements.	66,009