The estimated respondent count per year is approximately 3,000 families and 1,000 professionals.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
F2F HIC Feedback Survey	4,000	1	4,000	0.15	600
F2F HIC Grant Recipient Activity	51	1	51	89	4,539
Total	4,051		4,051		5,139

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–03455 Filed 2–20–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

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 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: National Eye Institute Special Emphasis Panel; NEI Mentored Career Development Award and Pathways to Independence Applications (K).

Date: March 13, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Jeanette M. Hosseini, Ph.D., Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892, 301–451–2020, *jeanetteh@mail.nih.gov*.

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Clinical, Epidemiological and Secondary Data Analysis Applications.

Date: March 22, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Brian Hoshaw, Ph.D., Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, Rockville, MD 20892, 301–451–2020, *hoshawb@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: February 15, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–03473 Filed 2–20–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice to Close Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as 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: National Institute of Nursing Research Special Emphasis Panel; NINR Centers Meeting.

Date: March 5–6, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Weiqun Li, MD, Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd., Suite 710, Bethesda, MD 20892, (301) 594–5966, *wli@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: February 15, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–03475 Filed 2–20–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-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 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., Shanda Finnigan, MPH, RN, CCRC, or Jacquelyn Goldberg, JD, 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: *ctsuconstact@westat.com.* 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 Contract Forms and Surveys 0925–0753 Expiration Date 06/30/2020 ICR Type: 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 CRF 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 CRF 312.53). Information is also collected through surveys to assess satisfaction, provide feedback to guide improvements with processes and technology, and assess health professional's interests in clinical trials.

To increase efficiencies, reduce administrative burden and cost, CTEP has requested consolidation of their current OMB submission. Consolidation is justified because although the various branches and contracts are responsible for distinct services, the processes that support the NCI and participating clinical sites efforts are intertwined. This revision of the previous submission includes changes to the NCI CIRB and CTSU form collections and integrates the Clinical Trials Monitoring Branch (CTMB) and Pharmaceutical Management Branch (PMB) form collections related to site audit and clinical investigator and key clinical site staff registration.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 68,855.

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 Roster Update Form (Attachment A05).	Health Care Practitioner	600	1	5/60	50
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
Site Initiated Data Update Form (Attachment A08).	Health Care Practitioner	2	12	10/60	4
Data Clarification Form (Attachment A09).	Health Care Practitioner	150	24	10/60	600
RTOG 0834 CTSU Data Transmittal Form (Attachment A10).	Health Care Practitioner	12	76	10/60	152
CTSU Generic Data Transmittal Form (Attachment A12).	Health Care Practitioner	5	12	10/60	10
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

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 System Access Request Form (Attachment A17).	Health Care Practitioner	180	1	20/60	60
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	2,000
CTSU PDF 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
NCI Adult/Pediatric 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

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 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	20/60	1,600
Study Closure or Transfer of Study Review Responsibility(Attachment B43).	Health Care Practitioner	1,680	1	20/60	560
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).		60	1	20/60	20
CTSU OPEN Survey (Attachment C03).	Health Care Practitioner	60	1	15/60	15
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
Concept Clinical Trial Survey (Attachment C09).	Health Care Practitioner	500	1	5/60	42
Prospective Clinical Trial Survey (Attachment C10).	Health Care Practitioner	1,000	1	1/60	17
Low Accrual Clinical Trial Survey (Attachment C11).	Health Care Practitioner	1,000	1	1/60	17
Audit Scheduling Form (Attachment D01).	Group/CTMS Users	152	5	21/60	266
Preliminary Audit Findings Form (Attachment D02).	Auditor	152	5	10/60	127
Audit Maintenance Form (Attachment D03).	Group/CTMS Users	152	5	9/60	114
Final Audit Finding Report Form (Attachment D04).	Group/CTMS Users	75	11	1,098/60	15,098
Follow-up Form (Attachment D05)	Group/CTMS Users	75	7	27/60	236
Roster Maintenance Form (Attachment D06).	CTMS Users	5	1	18/60	2
Final Report and CAPA Request Form (Attachment D07).	CTMS Users	12	9	1,800/60	3,240
NCI/DCTD/CTEP FDA Form 1572 for Annual Submission(Attachment E01).	Physician	23,000	1	8/60	3,067
NCI/DCTD/CTE Biosketch (Attachment E02).	Physician; Health Care Practitioner	33,000	1	47/60	25,850
NCI/DCTD/CTEP Financial Disclosure Form (Attachment E03).	Physician; Health Care Practitioner	33,000	1	5/60	2,750
NCI/DCTD/CTEP Agent Shipment Form (ASF) (Attachment E04).	Physician	23,000	1	7/60	2,683
Totals		136,487	207,989		68,855

Dated: January 23, 2018.

Karla Bailey,

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

[FR Doc. 2018–03471 Filed 2–20–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

A Strategic Roadmap for Establishing New Approaches To Evaluate the Safety of Chemicals and Medical Products in the United States; Availability of Report

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) coordinated the development of a strategic roadmap for establishing new approaches to evaluate the safety of chemicals and medical products in the United States. This document, prepared with support from the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), is now available.

ADDRESSES: The report is available at *https://ntp.niehs.nih.gov/go/natl-strategy.*

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: *warren.casey@nih.gov;* telephone: (984) 287–3118.

SUPPLEMENTARY INFORMATION:

Background: Scientific and technological advances in toxicology can significantly improve and protect public health. However, a national strategy is required to ensure the safe, effective, and timely implementation of human-based, predictive approaches in toxicity testing.

The goal of the U.S. Strategic Roadmap is to realize the vision set forth in the seminal National Research Council report ''Toxicity Testing in the 21st Century: A Vision and a Strategy.'' This 2007 report envisioned using human-based assays and model information to provide a more efficient, predictive, and economic system for assessing the effects of chemicals on human health.

The U.S. Strategic Roadmap was developed with participation from the 16 ICCVAM member agencies and multiple interagency workgroups, as well as input from a broad range of stakeholder groups. It describes a new framework that will enable development, establish confidence in, and ensure use of new approaches to toxicity testing that improve human health relevance and reduce or eliminate the need for testing in animals.

Summary of Report Contents: The successful development and implementation of new approaches to toxicity testing will require coordinated efforts that address three strategic goals:

- Connect end users with developers of new approach methodologies
- Foster the use of efficient, flexible, and robust practices to establish confidence in new methods
- Encourage the adoption and use of new methods and approaches by federal agencies and regulated industries

Implementation of the roadmap goals, already underway in specific testing areas, will include key elements needed for advancement of alternative methods.

Availability of Report: The report is available at *https://ntp.niehs.nih.gov/go/natl-strategy.*

Background Information on ICCVAM and NICEATM: ICCVAM is an interagency committee composed of representatives from 16 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine (enhance animal well-being and lessen or avoid pain and distress) animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) establishes ICCVAM as a permanent interagency committee of the National Institute of Environmental Health Sciences and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. ICCVAM acts to ensure that new and revised test methods are validated to meet the needs of federal agencies, increase the efficiency and effectiveness and federal agency test method review, and optimize utilization of scientific expertise outside the federal government. Additional information about ICCVAM can be found at *http://ntp.niehs.nih.gov/go/iccvam.*

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative testing approaches for validation studies and technical evaluations. Additional information about NICEATM can be found at *http://ntp.niehs.nih.gov/go/niceatm.*

Dated: February 9, 2018.

Brian Berridge,

Associate Director, National Toxicology Program.

[FR Doc. 2018–03476 Filed 2–20–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke: Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

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 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: National Institute of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders K; NSD–K Review Meeting.

Date: March 2, 2018.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–435–6033, *rajarams@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.