biospecimen inventories must register for an account.

Information will be collected from those wishing to create an account, sufficient to identify them as unique Users. Those submitting or requesting data and/or biospecimen inventories will be required to provide additional supporting information to ensure proper use and security of NICHD DASH study data and biospecimen inventories. The information collected is limited to the essential data required to ensure the management of Users in NICHD DASH is efficient and the sharing of data and biospecimens among investigators is effective. The primary uses of the information collected from Users by NICHD will be to:

- Communicate with the Users with regards to their data submission, data requests and biospecimen requests
- Monitor data submissions, data requests and biospecimen requests
- Notify interested recipients of updates to data and biospecimen inventories stored in NICHD DASH
- Help NICHD understand the use of NICHD DASH study data and biospecimen inventories by the research community

All the data collected from use of NICHD DASH except for information provided in the annual progress reports are for the purposes of internal administrative management of NICHD DASH. Information gathered through the annual progress reports may be used in publications describing performance of the DASH system.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 204.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of form	Number of respondents	Frequency of response	Average time per response (in hours)	Total annual burden hour
User Registration	200	1	5/60	17
Data and Biospecimen Inventory Submission	36	1	2	72
Data Request	60	1	1	60
Biospecimen Request	36	1	1	36
Data Use Annual Progress Report	60	1	10/60	10
Biospecimen Use Annual Progress Report	36	1	10/60	6
Institutional Certification Template	36	1	5/60	3
Total	200	200		204

Dated: April 17, 2018.

Jennifer M. Guimond,

Project Clearance Liaison, Eunice Kennedy Shriver, National Institute of Child Health and Human Development, National Institutes of Health.

[FR Doc. 2018–08901 Filed 4–26–18; 8:45 am]

BILLING CODE 4140–01–P

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/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Michael Montello, Pharm.D., Shanda Finnigan, MPH, RN, CCRC or Jacquelyn Goldberg, JD, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, 9609 Medical Center Drive, Rockville, MD 20850 or call non-toll-free number (240–276–6080) or email your request, including your address to: *ctsucontact@westat.com.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on February 21, 2018, page 7483 (83 FR 7483) 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: CTEP Branch and Support Contracts Forms and Surveys, 0925–0753 Expiration Date 06/30/2020, 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 112,798.

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
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

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
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
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

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
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	3240
NCI/DCTD/CTEP FDA Form 1572 for Annual Submission (Attachment E01).	Physician	23,000	1	15/60	5,750
NCI/DCTD/CTE Biosketch (Attachment E02)	Physician; Health Care Practitioner.	33,000	1	120/60	66,000
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	10/60	3,833
Totals		136,487	207,989		112,838

Dated: April 12, 2018.

Karla Bailey,

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

[FR Doc. 2018–08902 Filed 4–26–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Metabolic Reprogramming to Improve Immunotherapy.

Date: May 22, 2018.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Malaya Chatterjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, (301) 806–2515, *chatterm@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group; Cellular and Molecular Immunology—B Study Section.

Date: May 23–24, 2018.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree by Hilton Washington/Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Contact Person: Betty Hayden, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4206, MSC 7812, Bethesda, MD 20892, 301–435–1223, *haydenb@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Bioengineering Sciences and Technologies: AREA Review.

Date: May 24, 2018.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: David Filpula, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6181, MSC 7892, Bethesda, MD 20892, 301–435–2902, *filpuladr@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: April 23, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–08843 Filed 4–26–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed 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: Center for Scientific Review Special Emphasis Panel; AIDS and Related Research Special Topics.

Date: April 26, 2018.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).