DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in section 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Heart, Lung, Blood and Sleep Conference Support Applications.

Date: December 12–13, 2016.

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, Room 7196, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Stephanie J. Webb, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892, 301–435–0291, *stephanie.webb@nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; R25 Diversity: Short-Term Research Education to Increase Diversity.

Date: December 12, 2016.

Time: 10:00 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Stephanie L. Constant, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, 301–443–8784, *constantsl@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 16, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–27997 Filed 11–21–16; 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; Materials To Support NIH Serving as an IRB of Record or a Single IRB for Outside Institutions (Office of the Director)

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. This proposed information collection was previously published in the **Federal Register** on August 22, 2016, page 56667 (81 FR 56667) 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.

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 items(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: Julia Slutsman, Health Science Policy Analyst, Office of Human Subjects Research Protections (OHSRP), IRP, OD, NIH, Building 10, Room 1C154, 10 Center Drive, Bethesda, MD 20892, or call non-toll-free number 301–402–3444 or email your request, including your address to: *PHERRB@mail.nih.gov.* Formal requests for additional materials must be requested in writing.

SUPPLEMENTARY INFORMATION: The Office of Human Subjects Research Protections (OHSRP), Office of the Director (OD), 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 has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Materials to Support NIH Serving As an IRB of Record or a Single IRB for Outside Institutions, 0925-New, Office of Human Subjects Research Protections (OHSRP), Office of the Director, National Institutes of Health (NIH).

Need and Use of Information Collection: The NIH Human Research Protections Program (HRPP) is preparing to implement the recent ''NIH Policy on the Use of a Single Institutional Review Board (sIRB) of Record for Multi-Site Research,'' which requires the use of a single IRB of record for human subject protections review of certain multisite studies. Additionally, the NIH and HHS have recently established the Public Health Emergency Research Review Board (PHERRB) mechanism, for human subject protections review of certain—typically multisite—public health emergency research studies. Any of the 12 NIH intramural IRBs can be designated to serve as the PHERRB for review of a public health emergency research protocol. Finally, proposed changes to federal human subject protections regulations, if finalized, will require the use of single IRB review for the majority of HHS funded, multi-site studies.

To meet all of these needs, and support efficient single IRB review, researchers at outside institutions will need to provide information to the NIH HRPP, which includes the NIH intramural IRBs, using materials developed by the NIH Office of Human Subject Protections. The required materials include: The Application for PHERRB Review (APR); the Initial Review Local Context Worksheet (IRLCW); and the Continuing Review Local Context Worksheet (CRLCW). This information collection is intended to provide the NIH HRPP and the NIH IRBs with information necessary for NIH to maintain regulatory compliance in its conduct of human subject protections review when an NIH IRB serves an IRB of record for multisite research and to provide high quality and timely human subject protections reviews.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annual burden hours are 790.

ESTIMATED ANNUALIZED BURDEN HOURS

Data collection activity	Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average time per response (in hours)	Estimated total annual burden hours
APR	Principal Investigator (MD or PhD)	20	1	2	40
IRLCW	Principal Investigator (MD or PhD degree) or Research Coordinator (RN, BA, MA degree) or Regulatory Staff (BA degree).	250	1	2	500
CRLCW	Principal Investigator (MD or PhD degree) or Research Coordinator (RN, BA, MA degree) or Regulatory Staff (BA degree).	250	1	1	250
Total		520	520		790

Dated: November 16, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016–28140 Filed 11–21–16; 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 Trials Support Unit (National Cancer Institute)

AGENCY: National Institutes of Health.

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., 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.* 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 Trials Support Unit (CTSU) (NCI), 0925–0624, EXTENSION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Cancer Therapy Evaluation Program (CTEP) establishes and supports programs to facilitate the participation of qualified investigators on CTEP-supported studies, and to institute programs that minimize redundancy among grant and contract holders, thereby reducing overall cost of maintaining a robust treatment trials program. Currently guided by the efforts of the Clinical Trials Working Group (CTWG) and the Institute of Medicine (IOM) recommendations to revitalize the Cooperative Group program, CTEP has funded the Cancer Trials Support Unit (CTSU). The CTSU collects standardized forms to process site regulatory information, changes to membership, patient enrollment data, and routing information for case report forms. In addition, CTSU collects annual surveys of customer satisfaction for clinical site staff using the CTSU Help Desk, the CTSU Web site, and the Protocol and Information Office (PIO). An ongoing user satisfaction survey is in place for the Oncology Patient Enrollment Network (OPEN). User satisfaction surveys are compiled as part of the project quality assurance activities and are used to direct improvements to processes and technology.

OMB approval for an extension to the existing approval is requested for one year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 25,204.

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 hour
CTSU IRB/Regulatory Approval Transmittal Form.	Health Care Practitioner	9,000	12	2/60	3,600
CTSU IRB Certification Form	Health Care Practitioner	8,500	12	10/60	17,000
CTSU Acknowledgement Form	Health Care Practitioner	500	12	5/60	500
Withdrawal from Protocol Participation Form	Health Care Practitioner	50	12	5/60	50