

As the Exchanges mature and enrollment in QHPs expands, we will consider reporting the QRS at more granular levels (that is, QHP metal levels as defined in section 1302(d)(1) of the Affordable Care Act). We will also consider the development of a quality rating system applicable to other Exchange offerings, such as stand-alone dental plans, catastrophic plans and health care saving accounts.

**VI. Collection of Information Requirements**

This document does not impose information collection and recordkeeping requirements. However, it does make reference to an information collection activity. The aforementioned Enrollee Satisfaction Survey is currently seeking OMB approval via notice and comment periods separate from this proposed notice. The 60-day **Federal Register** notice published on June 28, 2013. Additionally, in future rulemaking, we will identify information collection requirements associated with the QRS and solicit public comment at that time.

Dated: November 6, 2013.

**Marilyn Tavenner,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2013-27649 Filed 11-14-13; 4:15 pm]

BILLING CODE 4120-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-Day Comment Request: NIH NCI Central Institutional Review Board (CIRB) Initiative (NCI)**

**SUMMARY:** Under the provisions of 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. This proposed information collection was previously published in the **Federal Register** on August 22, 2013, Vol. 78, P. 52204 and allowed 60-days for public comment. There were no public comments received. The purpose of this notice is to allow an additional 30 days for public comment. 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.

**Direct Comments to OMB:** 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: NIH Desk Officer.

**Comment Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**FOR FURTHER INFORMATION:** To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: CAPT Michael Montello, Pharm. D., MBA, Cancer Therapy Evaluation Program, Operations and Informatics Branch, 9609 Medical Center Drive, Rockville, MD 20850 or call non-toll-free number 240-276-6080 or Email your request, including your address to: *mike.montello@nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

**Proposed Collection:** NIH NCI Central Institutional Review Board (CIRB) Initiative (NCI), 0925-0625, Expiration Date 1/31/2014, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

**Need and Use of Information Collection:** The National Cancer Institute (NCI) Central Institutional Review Board (CIRB) provides a centralized approach to human subject protection and provides a cost efficient approach avoiding duplication of effort at each institution. The CIRB provides the services of a fully constituted IRB and provides a comprehensive and efficient mechanism to meet regulatory requirements pertaining to human subject protections including: initial reviews, continuing reviews, review of amendments, and adverse events. The Initiative consists of three central IRBs: Adult CIRB—late phase emphasis, Adult CIRB—early phase emphasis, and Pediatric CIRB. CIRB membership includes oncology physicians, surgeons, nurses, patient advocates, ethicists, statisticians, pharmacists, attorneys and other health professionals. The benefits of the CIRB Initiative reaches research participants, investigators and research staff, Institutional Review Boards (IRB), and Institutions. Benefits include: study participants having dedicated review of NCI-sponsored trials for participant protections, access to more trials more quickly and access to trials for rare diseases, accrual to trials begin more rapidly, ease of opening trials, elimination of need to submit study materials to local IRBs, and elimination of the need for a full board review. The benefits to the National Clinical Trials Network and Experimental Therapy-Clinical Trials Network include a cost efficient approach that avoids duplication of efforts at each institution. A variety of information collection tools are needed to support NCI's CIRB activities which include: worksheets, forms and a survey that is provided to all customers contacting the CIRB helpdesk.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,199.

**ESTIMATES OF ANNUAL BURDEN HOURS**

Form name	Type of respondents	Number of respondents	Frequency of responses per respondent	Average burden per response (in hours)	Total annual burden hours
CIRB Customer Satisfaction Survey .....	Participants/Board Members.	1,500	1	10/60	250
Request for 30 Day Website Access Form .....	Participants .....	25	1	10/60	4
Authorization Agreement and Division of Responsibilities between the NCI CIRB and Signatory Institution.	Participants .....	340	1	30/60	170
NCI CIRB Signatory Enrollment Form .....	Participants .....	40	1	4	160
IRB Staff at Signatory Institution's IRB .....	Participants .....	25	1	10/60	4
Investigator at Signatory Institution .....	Participants .....	65	1	10/60	11
Research Staff at Signatory Institution .....	Participants .....	65	1	10/60	11

## ESTIMATES OF ANNUAL BURDEN HOURS—Continued

Form name	Type of respondents	Number of respondents	Frequency of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Investigator at Affiliate Institution with an IRB .....	Participants .....	25	1	10/60	4
Research Staff at Affiliate Institution with an IRB ...	Participants .....	25	1	10/60	4
Investigator at Affiliate Institution without an IRB ....	Participants .....	25	1	10/60	4
Research Staff at Affiliate Institution without an IRB	Participants .....	25	1	10/60	4
Institutional Contact for Signatory Institution .....	Participants .....	65	1	10/60	11
IRB at Signatory Institution .....	Participants .....	25	1	10/60	4
Component Institution at Signatory Institution .....	Participants .....	65	1	10/60	11
IRB at Affiliate Institution .....	Participants .....	25	1	10/60	4
Affiliate Institution without an IRB .....	Participants .....	25	1	10/60	4
Facilitated Review Acceptance Form .....	Participants .....	300	1	10/60	50
Study Review Responsibility Transfer Form .....	Participants .....	80	1	10/60	13
Annual Signatory Institution Worksheet About Local Context.	Participants .....	120	1	20/60	40
Annual Principal Investigator Worksheet About Local Context.	Participants .....	120	1	20/60	40
Study-Specific Worksheet About Local Context .....	Participants .....	220	1	20/60	73
Study Closure or Transfer of Study Review Responsibility Form.	Participants .....	120	1	10/60	20
Potential Unanticipated Problem or Serious or Continuing Noncompliance Reporting Form.	Participants .....	120	1	15/60	30
Add or Remove Signatory and/or Component Institution Personnel.	Participants .....	120	1	10/60	20
Add or Remove Affiliate Institution Personnel .....	Participants .....	120	1	10/60	20
Add or Remove Component Institution .....	Participants .....	120	1	10/60	20
Add or Remove Affiliate Institution .....	Participants .....	120	1	10/60	20
One Time Study Roll Over Worksheet .....	Participants .....	120	1	10/60	20
Change of Signatory Institution PI Form .....	Participants .....	120	1	10/60	20
CIRB Board Member Biographical Sketch Form .....	Board Members .....	25	1	15/60	6.25
CIRB Board Member Contact Information Form .....	Board Members .....	25	1	10/60	4
CIRB Board Member W-9 .....	Board Members .....	25	1	15/60	6
CIRB Board Member Non-Disclosure Agreement (NDA).	Board Members .....	25	1	10/60	4
CIRB Direct Deposit Form .....	Board Members .....	25	1	15/60	6
NCI Adult/Pediatric CIRB Application for Treatment Studies.	Participants .....	25	1	2	50
NCI Adult/Pediatric CIRB Application for Ancillary Studies.	Participants .....	10	1	2	20
NCI Adult/Pediatric CIRB Application for Continuing Review.	Participants .....	80	1	1	80
Summary of CIRB Application Revisions .....	Participants .....	20	1	30/60	10
Locally-Developed Material Submission Form .....	Participants .....	15	1	15/60	4
Application Request to Review Translated Documents.	Participants .....	15	1	15/60	4
Adult Initial Review of Cooperative Group Protocol	Board Members .....	15	1	4	60
Pediatric Initial Review of Cooperative Group Protocol.	Board Members .....	15	1	4	60
Adult Continuing Review of Cooperative Group Protocol.	Board Members .....	130	1	1	130
Pediatric Continuing Review of Cooperative Group Protocol.	Board Members .....	70	1	1	70
Adult Amendment of Cooperative Group Protocol ..	Board Members .....	10	1	2	20
Pediatric Amendment of Cooperative Group Protocol.	Board Members .....	10	1	2	20
Adult Cooperative Group Response to CIRB Review.	Participants .....	15	1	1	15
Pediatric Cooperative Group Response to CIRB Review.	Participants .....	10	1	1	10
Adult Pharmacist's Review of a Cooperative Group Study.	Board Members .....	10	1	2	20
Pediatric Pharmacist's Review of a Cooperative Group Study.	Board Members .....	20	1	2	40
CIRB Statistical Reviewer Form .....	Board Members .....	30	1	30/60	15
Determination of Unanticipated Problem (UP) and/or Serious or Continuing Noncompliance (SCN).	Board Members .....	40	1	10/60	7
Adult Expedited Amendment Review .....	Board Members .....	350	1	30/60	175
Ped Expedited Amendment Review .....	Board Members .....	150	1	30/60	75
Adult Expedited Continuing Review .....	Board Members .....	120	1	30/60	60
Ped Expedited Continuing Review .....	Board Members .....	70	1	30/60	35
Adult Expedited Study Closure .....	Board Members .....	20	1	20/60	7

ESTIMATES OF ANNUAL BURDEN HOURS—Continued

Form name	Type of respondents	Number of respondents	Frequency of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Ped Expedited Study Closure .....	Board Members .....	20	1	20/60	7
Adult Expedited Study Chair Response to Required Mod.	Board Members .....	350	1	15/60	88
Ped Expedited Study Chair Response to Required Mod.	Board Members .....	150	1	15/60	38
Reviewer Worksheet of Translated Documents .....	Board Members .....	15	1	15/60	4
Reviewer Advertisement Checklist .....	Board Members .....	10	1	20/60	3

Dated: November 7, 2013.  
**Vivian Horovitch-Kelley**,  
*Program Analyst, National Institutes of Health.*  
 [FR Doc. 2013-27556 Filed 11-18-13; 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: Cancer Trials Support Unit (CTSU) (NCI)**

**SUMMARY:** Under the provisions of 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. This proposed information collection was previously published in the **Federal Register** on August 30, 2013, Vol. 78, p. 53763 and allowed 60-days for public comment. There have been no public comments. The purpose of this notice is to allow an additional 30 days for public comment. 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.

*Direct Comments to OMB:* 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: NIH Desk Officer.

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Michael Montello, 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: *montellom@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

*Proposed Collection:* Cancer Trials Support Unit (CTSU) (NCI), 0925-0624, Expiration Date 12/31/2013, REVISION, 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. Additionally, there are three surveys that collect information about health professional's interests in clinical trial, potential issues with opening and accruing to a clinical trial and reasons for low accrual.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 25,205.

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 .....	Health Care Practitioner	500	12	5/60	500
Withdrawal from Protocol Participation Form .....	Health Care Practitioner	50	12	5/60	50
Site Addition .....	Health Care Practitioner	25	12	5/60	25
CTSU Roster Update Form .....	Health Care Practitioner	50	12	4/60	40
CTSU Radiation Therapy Facilities Inventory Form.	Health Care Practitioner	20	12	30/60	120