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