Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street NW., 2nd Floor, Washington, DC 20405–0001, telephone (202) 501–4755. Please cite OMB Control No. 9000–0136 regarding Commercial Item Acquisitions in all correspondence.

Dated: August 22, 2013.

Karlos Morgan,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request Cancer Trials Support Unit (CTSU) (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on 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.

To Submit Comments and For Further Information: 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, 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.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

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.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 24,996.

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
CTSU IBCSG Drug Accountability Form	Health Care Practitioner	11	12	10/60	22
CTSU IBCSG Transfer of Investigational Agent Form.	Health Care Practitioner	3	12	20/60	12
Site Initiated Data Update Form	Health Care Practitioner	10	12	10/60	20
Data Clarification Form	Health Care Practitioner	341	12	20/60	1,364
RTOG 0834 CTSU Data Transmittal Form	Health Care Practitioner	60	12	10/60	120
MC0845(8233) CTSU Data Transmittal	Health Care Practitioner	50	12	10/60	100
CTSU Generic Data Transmittal Form	Health Care Practitioner	500	12	10/60	1,000
CTSU Patient Enrollment Transmittal Form	Health Care Practitioner	200	12	10/60	400
CTSU P2C Enrollment Transmittal Form	Health Care Practitioner	15	12	10/60	30
CTSU Transfer Form	Health Care Practitioner	20	12	10/60	40
CTSU System Account Request Form	Health Care Practitioner	20	12	20/60	80
CTSU Request for Clinical Brochure	Health Care Practitioner	75	12	10/60	150

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 hour
CTSU Supply Request Form	Health Care Practitioner	75	12	10/60	150
CTSU Web Site Customer Satisfaction Survey	Health Care Practitioner	275	1	15/60	69
CTSU Helpdesk Customer Satisfaction Survey	Health Care Practitioner	325	1	15/60	81
CTSU OPEN Survey	Health Care Practitioner	60	1	15/60	15
PIO Customer Satisfaction Survey	Health Care Practitioner	100	1	5/60	8

Dated: August 26, 2013.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–13–13AGH]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to Kimberly S. Lane, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Examining Traumatic Brain Injury in Youth—NEW—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Traumatic brain injury (TBI) is one of the highest priorities in public health because of its magnitude, economic and human impact, and preventability. The Centers for Disease Control and Prevention (CDC) estimates that approximately 1.7 million TBIs are sustained in the United States annually, either alone or in conjunction with another injury or condition. These figures may be an underestimation as they do not include people who are treated in physicians' offices or outpatient facilities, those who did not seek medical care, military personnel, or Americans living abroad. Moreover, the number of sports and recreation-related TBIs treated in U.S. emergency departments is increasing and has increased steadily since the early 2000s. Children, ages 0 to 4 years and adolescents, ages 15–19, are at the greatest risk of sustaining a TBI. A TBI is caused by a bump, blow or jolt to the head or a penetrating head injury that disrupts the normal function of the brain. The severity of a TBI may range from ''mild'' (a brief change in mental status or consciousness) to ''severe'' (an extended period of unconsciousness or amnesia after the injury).

In 1996, Congress passed Public Law 104–166, the Traumatic Brain Injury Act, which charged CDC with implementing projects to reduce the incidence of traumatic brain injury. The CDC definition of TBI uses selected codes of the International Classification of Diseases, 9th Clinical Modification (ICD–9 CM) to identify cases of TBI from hospital and non-hospital databases containing billing records for services rendered to patients. It is thought, however, that the ICD–9 CM codes currently used in CDC's surveillance system to capture cases of TBI are not sufficiently sensitive to capture diagnosed TBI. CDC, therefore, would like to collect de-identified medical information of a representative sample of pediatric patients, from two clinical settings, who received a confirmed diagnosis of mild to severe TBI and link these patients to their administrative medical claims forms. Collectively, the data will allow CDC to estimate the sensitivity of currently utilized ICD–9 CM codes to capture cases of diagnosed TBI, as well as ICD–9 CM codes not currently being utilized that may improve the sensitivity to capture cases of TBI. We propose to conduct a retrospective cross-sectional study of a random sample of patients with a suspected TBI within two clinical settings (Emergency Departments and Concussion Clinics).

Information for this study is being collected to better understand the coding practices related to TBI among children within multiple clinical settings. The data will benefit public health by providing a more accurate case definition of TBI for the Central Nervous System (CNS) Injury Surveillance. Results from this study will be shared with CDC stakeholders, such as state and local health departments, clinicians and TBI-related medical researchers through CDC reports and peer-reviewed publications.

CDC requests OMB approval for three years to abstract data from medical and billing records dated April 1st to September 30, 2013. Data will be collected electronically, analyzed with findings compiled in a final report. The following information is needed from the medical record: Age at injury, encrypted or randomly generated identification number (that can be linked to billing system), head injury assessment value (indicator variable, Yes/No), Traumatic injury mechanism, Glasgow Coma Scale (GCS) score, ICD–9 CM codes and External cause of injury (E) codes if available, Head injury assessment value (indicator), Confirmed Diagnosis of TBI (Yes/No), based on the TBI case definition and if yes, Injury Type. The necessary data fields from the hospital billing system are: Encrypted or randomly generated identification number (that can be linked to medical chart), diagnosis codes (all available