



National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

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To: Office of Management and Budget (OMB)

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Subject: Cancer Trials Support Unit (CTSU) Public Use Forms and Customer Satisfaction Surveys (NCI)

This is a request for OMB to approve the Existing Collection in Use without an OMB number titled, "Cancer Trials Support Unit (CTSU)" for 3 years. The Federal Register Notices, supporting statements, and various attachments accompany this memorandum.

The Public Health Service Act, and Section 413 (42 USC § 285a-2) authorizes Cancer Therapy Evaluation Program (CTEP) to establish and support 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. Based upon the recommendations of the Armitage report in the late 1990's and currently guided by the efforts of the Clinical Trials Working Group (CTWG), CTEP has funded the CTSU.

Cancer Trial Support Unit (CTSU) collects annual surveys of customer satisfaction for clinical site staff using the CTSU Help Desk and the CTSU web site. 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. In addition, the CTSU collects standardized forms to process site regulatory information, changes to membership, patient enrollment data, and routing information for case report forms. It is estimated that there will be 21,770 respondents per year and 27,861 hours of burden. Burden estimates are based on the number of forms at the site level that are returned, making it difficult to calculate the number of respondents and their frequency of responses. Additionally, not all institutions and CTSU members take part in all services and protocols.