



This document is scheduled to be published in the Federal Register on 02/09/2016 and available online at <http://federalregister.gov/a/2016-02447>, and on [FDsys.gov](http://FDsys.gov)

[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day comment request

Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute, 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. This proposed information collection was previously published in the Federal Register on November 17, 2015 page 71815 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. The National Cancer Institute, 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: Charles Hall, RPh, M.S., Chief, Pharmaceutical

Management Branch, Cancer Therapy Evaluation Program, National Cancer Institute, 9609 Medical Center Drive, RM 5W240, MSC 9725, Bethesda, Maryland 20892. Or call non-toll-free number (240) 2766575, or e-mail your request, include your address to: hallch@mail.nih.gov.

Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer, 0925-0613, Expiration Date 03/31/2016, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The U.S. Food and Drug Administration (FDA) holds the National Cancer Institute (NCI) responsible, as a sponsor of investigational drug trials, for the collection of information about the clinical investigators who participate in these trials and to assure the FDA that systems for accountability are being maintained by investigators in its clinical trials program. The information collected is used to identify qualified investigators and to facilitate the submission and distribution of important information relative to the investigational drug and the response of the patient to that drug. Investigators are physicians who specialize in the treatment of patients with cancer. Data obtained from the Drug Accountability Record is used to track the dispensing of investigational anticancer agents from receipt from the NCI to dispensing or administration to patients. NCI and/or its auditors use this information for compliance purposes. The frequency of Response is up to 16 times per year. The affected public is private sector including businesses, other for-profit organizations, and non-profit institutions. The type of respondents are investigators, pharmacists, nurses, pharmacy technicians, and data managers.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 14,649 hours.

Estimated Annualized Burden Hours

Table 1 Estimates of Annual Burden					
Type of Respondents	Form	Number of Respondents	Number of Responses	Average Time per Response (in Hours)	Total Hour Burden
Investigators and Designee for Investigator Registration and DARF	Statement of Investigator	22,283	1	15/60	5,571
	NCI/DCTD/CTEP Supplemental Investigator	22,283	1	10/60	3,714
	Financial Disclosure Forms	22,283	1	5/60	1,857
	NCI/DCTD/CTEP Drug Accountability Record Form (DARF and DARF-Oral)	3,288	16	4/60	3,507
Total		25,571	119,457		14,649

Dated: February 3, 2016.

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 Karla Bailey,  
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 National Cancer Institute, NIH.

[FR Doc. 2016-02447 Filed: 2/8/2016 8:45 am; Publication Date: 2/9/2016]