

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Report	600	1	600	1	600
Total	600	1	600	14	8,400

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: July 28, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; the Drug Accountability Record (Form NIH 2564) (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), the 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.

Proposed Collection

Title: The Drug Accountability Record (Form NIH 2564) (OMB No. 0925-0240). *Type of Information Collection Request:* Extension with changes. *Need and Use of Information Collection:* The Food and Drug Administration (FDA) regulations require investigators to establish a record of receipt, use and disposition of all investigational agents. The National Cancer Institute (NCI), as a sponsor of investigational agent trials, has the responsibility to assure the FDA that investigators in its clinical trials program are maintaining systems for agent accountability. In order to fulfill these requirements, a standard Investigational Drug Accountability Report Form (DARF) NIH-2564, was designed to account for agent

inventories and usage by protocols. The data obtained from the agent accountability record will be used to keep track of the dispensing of investigational agent anticancer agents to patients. It is used by the NCI management to ensure that investigational agent supplies are not diverted for inappropriate protocol or patient use. The information is also compared to patient flow sheets (protocol reporting forms) during site visits conducted for each investigator every three years. All comparisons are done with the intention of ensuring protocol, patient and agent compliance for patient safety and protection. *Frequency of Response:* Approximately 16 times per year. *Affected Public:* Private sector including businesses, other for-profit organizations, and non-profit institutions. *Type of Respondents:* Investigators, pharmacists, nurses, pharmacy technicians, and data managers. The annualized respondents' burden for record keeping is estimated to require 6,714 hours (Table 1). There are no capital costs, operating costs, or maintenance costs to report.

TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual burden hours
Investigators, or Designees	4,196	16	6/60 (0.1)	6,714

Request for Comments

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 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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Charles, Hall, RPh, M.S., Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, National Cancer Institute, Executive Plaza North, Room 7149, 9000 Rockville Pike, Bethesda, Maryland 20891. Or call non-toll-free number 301-496-5725 or e-mail your request, include your address to: *hallch@mail.nih.gov*.

Comments 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.

Dated: July 28, 2010.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010-19158 Filed 8-3-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Multi-Ethnic Study of Atherosclerosis (MESA) Event Surveillance

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