

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.*

[FR Doc. 2010-19121 Filed 8-3-10; 8:45 am]

**BILLING CODE 4165-15-P**

**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]

**BILLING CODE 4140-01-P**

**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

National Heart, Lung, and Blood Institute (NHLBI), 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:* Multi-Ethnic Study of Atherosclerosis (MESA) Event Surveillance. *Type of Information Request:* Renewal (OMB No. 0925–0493). *Need and Use of Information Collection:* The study, MESA, is identifying and quantifying factors associated with the presence and progression of subclinical

cardiovascular disease (CVD)—that is, atherosclerosis and other forms of CVD that have not produced signs and symptoms. The findings provide important information on subclinical CVD in individuals of different ethnic backgrounds and provide information for studies on new interventions to prevent CVD. The aspects of the study that concern direct participant evaluation received a clinical exemption from OMB clearance (CE–99–11–08) in April 2000. OMB clearance is being sought for the contact of physicians and participant proxies to obtain information about clinical CVD events

that participants experience during the follow-up period. *Frequency of response:* Once per CVD event. *Affected public:* Individuals. *Types of Respondents:* Physicians and selected proxies of individuals recruited for MESA. The annual reporting burden is as follows: *Estimated Number of Respondents:* 74; *Estimated Number of Responses per respondent:* 1.0; *Average Burden Hours Per Response:* 0.20; and *Estimated Total Annual Burden Hours Requested:* 14.7.

There are no capital, operating, or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Physicians .....	17	1.0	0.20	3.4
Proxies .....	57	1.0	0.20	11.3
Total .....	74	1.0	0.20	14.7

*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 will have practical utility; (2) The accuracy of the agency’s estimate of 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 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:* To request more information on the proposed project or to obtain a copy of data collection plans and instruments, contact Dr. Diane Bild, Division of Cardiovascular Sciences, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, Suite 10122, MSC # 7936, Bethesda, MD 20892–7936, or call non-toll-free number (301) 435–0457, or e-mail your request, including your address to: [bildd@nhlbi.nih.gov](mailto:bildd@nhlbi.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 27, 2010.  
**Suzanne Freeman,**  
*NHLBI Project Clearance Liaison, National Institutes of Health.*  
**Michael Lauer,**  
*Director, DCVS, National Institutes of Health.*  
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**BILLING CODE 4140–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; Comment Request; Assessing the Long-Term Impacts of the John E. Fogarty International Center’s Research and Training Programs**

*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 John E. Fogarty International Center, 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:* Assessing the Long-Term Impacts of the John E. Fogarty International Center’s Research and Training Programs.

*Type of Information Collection Request:* New collection.

*Need and Use of Information Collection:* This study will inform investment decisions and strategies employed by the Fogarty International Center for the purpose of strengthening biomedical research capacity in low and middle income countries. The primary objective of the study is to develop detailed case studies of the long-term impacts of Fogarty’s research and training programs on educational institutions located in low and middle income countries. The findings will provide valuable information concerning return on the Center’s investments over the past twenty years and effective strategies for promoting research capacity development in the future.

*Frequency of Response:* Once.  
*Affected Public:* Individuals.  
*Type of Respondents:* Current and former NIH grantees; Current and former NIH trainees in countries of interest; Leaders and administrators at institutions of interest; Policy-makers and scientific leaders in countries of interest.

*Estimated Number of Respondents:* 105 per institution; total of 10 institutions over five years.

*Estimated Number of Responses per Respondent:* 1.

*Average Burden Hours per Response:* 1 hour for interview participants; 2 hours for focus group participants.

*Estimated Total Annual Burden Hours Requested:* 290, and the annualized cost to respondents is estimated at \$4,841.