

objectives of the study are to: (1) Assess the NDPA award selection process; (2) determine if the program was implemented as planned; and (3) determine if the process was conducted in accordance with the overall mission of the NDPA program. The findings will provide valuable information concerning: (1) The characteristics of applicants and reviewers; (2) the criteria used to evaluate and select awardees;

and (3) aspects of the process that could be revised or improved.

*Frequency of Response:* Once. *Affected Public:* none. *Type of Respondents:* Applicants, Reviewers and Panelists, Liaisons. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. *Frequency of Response:* Once. *Affected Public:* none. *Type of Respondents:* Applicants, Reviewers and Panelists. *Estimated Number of Respondents:* 710; *Estimated Number of*

*Responses per Respondent:* 1. *Average Burden Hours Per Response:* .25 (15 minutes), and *Estimated Total Annual Burden Hours Requested:* 177.50 and the annualized cost to respondents is estimated at \$9,662.50. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. Table 1 and Table 2, respectively, present data concerning the burden hours and cost burdens for this data collection.

TABLE 1.—ANNUALIZED ESTIMATE OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time for response (hr)	Total hour burden *
Applicants .....	600	1	.25	150
Extramural evaluators .....	110	1	.25	2
Total .....	710	1	.25	177.50

\* Total Burden = N Respondents\*Response Frequency\*minutes to complete/60.

TABLE 2.—ANNUALIZED COST TO RESPONDENTS

Type of respondents	Number of respondents	Response frequency	Approx. hourly wage rate	Total respondent cost **
Applicants .....	1200	1	\$55.00	\$8,250
Extramural evaluators .....	220	1	55.00	1,512.50
Total .....	710	1	55.00	9,662.50

\*\* Total Respondent Cost = N Respondents\*Response Frequency\*minutes to complete/60\* hourly rate.

*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 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.

*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 G. Stephane Philogene, PhD, Assistant Director for Policy and Planning, Office of Behavioral and Social Sciences Research, National Institutes of Health, 31 Center Drive, Building 31, Room B2-

B37, Bethesda, MD 20892, or call non-toll-free number 301-402-3902, or E-mail your request, including your address to: [philoges@od.nih.gov](mailto:philoges@od.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: October 24, 2007.

**G. Stephane Philogene,**

*Assistant Director for Policy and Planning, Office of Behavioral and Social Sciences Research, National Institutes of Health.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission of OMB Review; Comment Request; Drug Accountability Record (NCI)**

*Summary:* In compliance with the requirement of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the

National Cancer Institute, the National Cancer Institute (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collected below. This proposed information collection was previously published in the **Federal Register** on August 13, 2007, Vol. 72, No. 55, Page 45251 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 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 December 1, 2007, unless it displays a valid OMB control number.

*Proposed Collection: Title:* Drug Accountability Record (NCI) (Form NIH 2564). *Type of Information Collection Request:* Extension, with no changes OMB No. 0925-0240. *Expiration Date:* 11/30/07. *Need and Use of Information Collection:* Food and Drug Administration (FDA) regulations require investigators to establish a record of the receipt, use and disposition of all investigational agents. The National Cancer Institute, (NCI), as

a sponsor of investigational drug trials, has the responsibility to assure the FDA that investigators in its clinical trials program are maintaining systems for drug accountability. In order to fulfill these requirements, a standard Investigational Drug Accountability Report Form (NIH 2564) was designed to account for drug inventories and usage by protocols. The data obtained from the drug accountability record will be used to keep track of the dispensing of investigational anticancer agents to patients. It is used by NCI management to ensure that investigational drug 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 once every three years. All comparisons are done with the intention of ensuring protocol, patient and drug compliance for patient and drug compliance for patient safety and protections.

*Frequency of Response:* Daily.

*Affected Public:* State or local governments, businesses or other for-profit. Federal agencies or employees, non-profit institutions, and small business or organizations.

*Type of Respondents:* Investigators, pharmacist, nurses, pharmacy technicians, data manager. The annual reporting burden is divided into two major areas. These are the audits of Drug Accountability Forms by Government and its contractors and the use of the forms by clinical research sites. The burden is as follows:

*Federal Burden:* 1700 audits are conducted of clinical research sites, a minimum of three Drug Accountability Forms are reviewed at the audit. Each form requires ½ hour to review.

*Number of Respondents:* 1700.

*Number of Responses per Respondent:* 3.

*Average Burden per Response:* 0.5 hours.

*Annual Burden Hours:* 2,250 hours.

*Clinical Trial Site Burden:* The annual respondents' burden for record keeping is estimated to require 6,240 hours. The record keeping burden represents an average time required for multiple entries (6 minutes or 0.1 hour per entry) on the drug accountability form, the average number of forms maintained by each record keeper and the number of record keepers.

#### **Drug Accountability Forms**

*Number of Record Keepers:* 3990.

*Number of Responses per Respondent:* 16.

*Average Burden per Response:* 0.1 (6 minutes).

*Annual Burden Hours:* 6,240 hours.

There are no Capital Costs, Operating Costs, and Maintenance Cost to report.

*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 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.

*Direct Comments to OMB:* Written comments or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response times, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Charles L. Hall, Jr., Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of the Cancer Treatment and Diagnosis, and Centers, National Cancer Institute, Executive Plaza North, Room 7148, 9000 Rockville Pike, Bethesda, MD 20892 or call non-toll-free number 301-496-5725 or e-mail your request, including your address to: [Hallch@mail.nih.gov](mailto:Hallch@mail.nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days following the date of this publication.

**Vivian Horovitch-Kelley,**

*NCI Project Clearance Liaison, National Institutes of Health.*

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## **DEPARTMENT OF HOMELAND SECURITY**

### **Federal Emergency Management Agency**

#### **Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice; 60-day notice and request for comments; revision of a currently approved collection, OMB Number 1660-0011, FEMA Form 22-13.

**SUMMARY:** The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed revised information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning an information collection system for disaster program accounts and debts receivable. The automated portion of the system is an accounts receivable system and is complimented by a manual technique that collects personal financial data directly from individual debtors by their completion of FEMA Form 22-13.

**SUPPLEMENTARY INFORMATION:** When errors in payments occur or reviews and audits determine that overpayments were made in various disaster entitlements, FEMA's Disaster Finance Branch (DFB), Office of the Chief Financial Officer (CFO) records pertinent receivable data, including individuals' personal data, within an automated, commercial, off-the-shelf (COTS) accounts receivable system—ACCPAC. Using various screens, a receivable is established to bill, monitor payments and produce reports. If, for lack of payment, an account receivable becomes a debt, ACCPAC continues as the receivable billing and collection system, but additional personal financial information is gathered and used to determine an ability to pay in setting requirements of installment payment agreements. DHS debt collection regulations, 6 CFR part 11, require FEMA to maintain current credit data on FEMA's debtors. To determine debtors' financial condition, this includes the individual debtors' own financial statements, executed under penalty for false claim, concerning their assets and liabilities and their income and expenses. FEMA Form 22-13 is the vehicle used to collect such data directly from the individual debtor.