Type of respondents	Estimated number of respondents	Estimated number of responses per respondent *	Average burden hours per response	Estimated total annual burden hours requested
Participant proxies	102	1.0	0.25	26
Total	3,330	3.76	0.246	1,029

* Total for 3 years.

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 CONTACT: To request more information on the proposed project or to obtain a copy of data collection plans and instruments, contact Dr. Jean Olson, Epidemiology and Biometry Program, Division of Clinical Applications, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, MSC #7934, Bethesda, MD 20892–7934, or call non-toll-free number (301) 435–0707, or e-mail your request, including your address to: *OlsonJ@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: March 16, 2004.

Peter Savage,

Director, DECA.

[FR Doc. 04–6732 Filed 3–24–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Proposed Collection; Comment Request; the Drug Accountability Record

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. *Type of Information Collection Request:* Revision. *Need and Use of Information Collection:* FDA regulations require *investigators:* To maintain adequate records of the disposition of all investigational drugs received from the sponsor; to prepare and maintain adequate case histories of treated patients and controls; and to furnish reports to the drug sponsor who is responsible for evaluating the results of the investigation. Similarly, 21 CFR 312.1 includes requirements for *sponsors* to maintain adequate records on the shipment of drugs to investigators; to make individual patient records available to the FDA for inspection; and to submit accurate progress reports of the drug investigation to the FDA. The NCI, as an IND sponsor has developed the ''Drug Accountability Record'' form (DARF: NIH 2564) to help investigators using NCI sponsored drugs under NCI protocols to meet FDA requirements. *Frequency of Response:* Daily. *Affected Public:* Individuals or households; businesses or other for-profit; not-for-profit institutions; Federal Government; State, local or tribal government. *Type of Respondents:* Pharmacists, nurses and investigators or their designee at medical institutions to keep track of the dispensing of investigational anticancer drugs to patients use the information entered onto the DARF. NCI uses the data from the DARF to ensure compliance with NCI's responsibilities as an IND sponsor. NCI Management request copies of the DARF at any time for audit and review and DARFs are reviewed at least once every 3 years during site audits. The information contained in the DARF is compared to PMB–IMS Inventory Module histories for each investigator and clinical site to ensure no diversion of investigational drug supplies to inappropriate protocol or patient use. The accountability information is also compared to patient flow sheets (protocol reporting forms) during site visits conducted for each investigator. All comparisons are completed with the intention of ensuring protocol integrity, patient safety, and compliance with FDA regulations. Record keeping of drug accountability information in a standard format is required to allow an investigator to receive, and continue to receive NCI-sponsored drugs. This information is reviewed at the time of site visit audits, which currently occur at least once every 3 years. The IND sponsor may also request the DARF at any time. This requirement is an essential part of investigational agent accountability process and motivates the investigator to maintain accurate, appropriate records. The record keeping retention period is specified by FDA regulation, and the NCI does not deviate from that requirement. As noted above, the FDA requires IND sponsors to maintain adequate records on the shipment and disposition of drugs to investigators. Permitting intra-institutional transfer of drugs to other NCI sponsored protocols and other approved investigators necessitates that NCI be notified of these transfers. It is for this purpose and use that the Transfer of Investigational Drug form (TID: NIH 2564–1) was developed. The annual reporting burden is as follows: *Estimated Number of Respondents:* 7,371; *Estimated Number of Responses per Respondent:* 8; *Average Burden Hours Per Response:* 0.67; and *Estimated Total Annual Burden Hours Requested:* 3,378. The annualized respondent's burden for record keeping is estimated to require 3,298 hours for the DARF and 80 hours for the TID form. The annualized cost to the respondents is estimated at $84,450.00. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

A.12–1 ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Drug Accountability Form				
Investigators, or Designees	6,171	8	0.0668 hours	3,298
Drug Transfer Form				
Investigators and/or their Designees	1,200	1	0.0668	80
Total Annual Hours for Investigators and/or their Designees				3,378

Estimate of Other Total Annual Cost Burden To Respondents or Record keepers: None.

Annualized Cost to the Federal Government: The annualized cost to the Federal government for printing is estimated at $4,000. The annualized cost to the Federal government for distributing the forms is estimated at $2,000.

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, R.PH., 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.nci.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: March 18, 2004.

Rachelle Ragland-Greene,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 04–6733 Filed 3–24–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Request for Applications for SAMHSA Dissertation Grants: Support for Analyses in Substance Abuse (PA 04–001)

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of request for applications for SAMHSA Dissertation Grants: Support for Analyses in Substance Abuse (PA 04–001).

Authority: Section 501(d)(8) of the Public Health Service Act.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA), Office of Applied Studies, is accepting applications for Fiscal Year 2004 grants to support dissertation research on involving data analysis on substance abuse services issues. The purpose of the program is to expand the number of researchers who conduct high-quality substance abuse services research, the study of how various factors (social, financial, organizational, and personal) affect the need for and access to substance abuse treatment, the quality and cost of substance abuse treatment, and, ultimately, health and well being. Students registered and in good standing at an accredited academic doctoral degree program (*e.g.,* Ph.D., Sc.D., or Dr.P.H.), which requires a dissertation based on original research, may apply. Students in such fields as sociology, psychology, social work, biostatistics, epidemiology, economics, policy, management, medicine, nursing, public health or health services research are especially encouraged to apply. The student must apply through a public or private nonprofit U.S. institution that will administer the grant on his or her behalf.

DATES: Applications are due on June 1, 2004.

FOR FURTHER INFORMATION CONTACT: For questions on program issues, contact: Sara Q. Duffy, Ph.D., Senior Economist, SAMHSA/Office of Applied Studies, 5600 Fishers Lane, Room 16–105, Rockville, MD 20857, Phone: (301) 443–8565; e-mail: *sduffy@samhsa.gov.*

For questions on grants management issues, contact: Gwendolyn Simpson, SAMHSA/Division of Grants Management, 5600 Fishers Lane, Room 13–103, Rockville, MD 20857, Phone: (301) 443–4456; e-mail: *gsimpson@samhsa.gov.*

SUPPLEMENTARY INFORMATION:

Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

SAMHSA Dissertation Grants: Support for Analyses in Substance Abuse (PA 04–001)

(Initial Announcement)

Catalogue of Federal Domestic Assistance (CFDA) No.: 93.243.

Key Dates

Application Deadline—Applications for FY2004 grants are due by June 1, 2004. The annual application receipt date for subsequent fiscal years will be May 1, or, if May 1 is a Saturday or Sunday, the following Monday.

Intergovernmental Review (E.O. 12372)—Letters from State Single Point of Contact (SPOC) are due no later than 60 days after application deadline.

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