

center networks in the implementation of comprehensive pharmacy services.

The estimated burden is as follows:

| Form name             | Number of respondents | Responses per respondent | Hours per response | Total burden hours |
|-----------------------|-----------------------|--------------------------|--------------------|--------------------|
| Baseline .....        | 1400                  | 1                        | .33                | 462                |
| Encounter data .....  | 1400                  | 4                        | .16                | 933                |
| Pharmacy Survey ..... | 14                    | 3                        | 1                  | 42                 |
| Total .....           | 1414                  | .....                    | .....              | 1437               |

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-22, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 27, 2001.

**Jane M. Harrison,**

Director, Division of Policy Review and Coordination.

[FR Doc. 01-5224 Filed 3-2-01; 8:45 am]

BILLING CODE 4160-15-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; Comment Request; Drug Accountability Record**

**SUMMARY:** Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) 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 December 14, 2000, pages 78175-78176, 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 October 1, 1995, unless it displays a currently valid OMB control number.

**Proposed Collection**

*Title:* Drug Accountability Record.  
*Type of Information Collection Request:* Revision. (OMB No. 0925-0240, expires 3/31/2001). *Need and use of Information Collection:* The regulations of the Food and Drug Administration (FDA) 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 for assuring to the FDA that systems for drug accountability are being maintained by investigators in its clinical trials program. In order to fulfill these requirements, we have developed two standardized forms. One, the investigational Drug Accountability Report Form (NIH 2564) designed to account for drug inventories and usage by protocol and the other, Transfer Investigational Drug Form (NIH-2564-1) that permits intra-institutional transfer of agents to NCI approved protocols for use by the investigator or other NCI registered investigators on approved protocols. The data obtained from the drug accountability record is used to track the dispensing of investigational anticancer drugs from receipt from NCI to dispensing or administration to patients. NCI uses the accountability data to ensure that investigational drug supplies are not diverted for inappropriate protocol or

patient use. The drug accountability information is used to validate patient protocol reporting forms during site audits conducted at each of the Cooperative Groups. The intent is to ensure the investigational agents are used according to protocol guidelines and to ensure the patient's safety and protection. *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. *Types of Respondents:* Investigators and their designees, pharmacists, nurses, pharmacy technicians, data managers. 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: The annualized respondents' burden for record keeping is estimated to require 2,436 hours for drug accountability and 80 hours for drug transfer. The reporting burden is the average time (4 minutes or 0.0668 hours) required to complete the transfer investigational drug form multiplied by the number of forms completed annually. The record keeping burden represents an average time required for multiple entries (4 minutes or 0.0668 hours per entry) on the drug accountability form, the average number of forms maintained by each record keeper and the number of record keepers. These estimates are based on the items shipped by the PMB and the number of transfer approvals in the calendar year 1999.

| Type of respondents              | Est. number of respondents | Est. number of responses/ respondents | Avg. burden hours per response | Avg. burden hours | Est. total annual burden hours requested |
|----------------------------------|----------------------------|---------------------------------------|--------------------------------|-------------------|--|
| Drug transfer, form .....        | 1,200                      | 1                                     | 0.0668                         | 80                | 80                                       |
| Drug, accountability, form ..... | 4,560                      | 8                                     | 0.0668                         | 2,436             | 2,436                                    |
| Total .....                      | 5,760                      | .....                                 | .....                          | .....             | 2,516                                    |

There are no Capital Costs to report. There are no Operating or Maintenance Costs 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 proposed performance of the functions of the agency, including whether the information shall 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 comment 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, 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 Carl Huntley, Head Drug Management and Authorization Section, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of Cancer Therapy and Diagnosis, National Cancer Institute, Executive Plaza North, Room 7112, 9000 Rockville Pike, Bethesda, Maryland 20892. Or call non-toll-free number 301-496-5725 or e-mail your request, include your address to [HuntleyC@ctep.nci.nih.gov](mailto:HuntleyC@ctep.nci.nih.gov).

#### Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before April 14, 2001.

Dated: February 26, 2001.

**Reesa Nichols,**

*NCI Project Clearance Liaison.*

[FR Doc. 01-5174 Filed 3-2-01; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of General Medical Sciences Initial Review Group, Biomedical Research and Research Training Review Subcommittee A.

*Date:* March 14, 2001.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

*Contact Person:* Carole H. Latker, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 1A5-13, Bethesda, MD 20892, (301) 594-2848, [latkerc@nigms.nih.gov](mailto:latkerc@nigms.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS).

Dated: February 20, 2001.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 01-5172 Filed 3-2-01; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Environmental Health Sciences Special Emphasis Panel, National Center for Toxicogenomics (NCT) Microarray Resource.

*Date:* March 14, 2001.

*Time:* 11 a.m. to 1 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* NC Biotechnology Center, 15 T.W. Alexander Drive, Post Office Box 13547, Research Triangle Park, NC 27709.

*Contact Person:* Linda K. Bass, Scientific Review Administrator, Nat'l Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-24, Research Triangle Park, NC 27709, (919) 541-1307.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences, National Institutes of Health, HHS)

Dated: February 23, 2001.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 01-5173 Filed 3-2-01; 8:45 am]

**BILLING CODE 4140-01-M**