

voluntary reporting will demonstrate the pharmaceutical manufacturer's good faith and willingness to work with governmental authorities to correct and remedy the problem. In addition, reporting such conduct will be considered a mitigating factor by the OIG in determining administrative sanctions (e.g., penalties, assessments, and exclusion), if the reporting company becomes the subject of an OIG investigation.¹⁸

When reporting to the government, a pharmaceutical manufacturer should provide all information relevant to the alleged violation of applicable Federal or state law(s) and the potential financial or other impact of the alleged violation. The compliance officer, under advice of counsel and with guidance from the governmental authorities, could be requested to continue to investigate the reported violation. Once the investigation is completed, and especially if the investigation ultimately reveals that criminal, civil or administrative violations have occurred, the compliance officer should notify the appropriate governmental authority of the outcome of the investigation, including a description of the impact of the alleged violation on the operation of the applicable Federal health care programs or their beneficiaries.

III. Conclusion

In today's environment of increased scrutiny of corporate conduct and increasingly large expenditures for prescription drugs, it is imperative for pharmaceutical manufacturers to establish and maintain effective compliance programs. These programs should foster a culture of compliance that begins at the executive level and permeates throughout the organization. This compliance guidance is designed to provide assistance to all pharmaceutical manufacturers as they either implement compliance programs or re-assess existing programs. The essential elements outlined in this

compliance guidance can be adapted to the unique environment of each manufacturer. It is the hope and expectation of the OIG that the resulting compliance programs will benefit not only Federal health care programs and their beneficiaries, but also pharmaceutical manufacturers themselves.

Dated: September 26, 2002.

Janet Rehnquist,

Inspector General.

[FR Doc. 02-25119 Filed 10-2-02; 8:45 am]

BILLING CODE 4152-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; California Health Interview Survey (CHIS) Cancer Control Module (CCM)

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 Institutes of Health (NIH), National Cancer Institute (NCI) 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: California Health Interview Survey (CHIS) Cancer Control Module (CCM). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* NCI sponsored a Cancer Control Modules to the National Health Interview Survey (NHIS) and to the California Health Interview Survey (CHIS) administered in 2000. While the NHIS data have proven extremely useful in monitoring risk factors and screening related to cancer control, the national sample does not provide adequate

numbers of racial-ethnic minorities to analyze particular domains within them, such as age by gender and income or education. The CHIS telephone survey, administered for the first time in 2000-2001, is designed to provide population-based, standardized health-related data for California counties. Initiated by the California Department of Health Services (CDHS) Center for Health Statistics, the Public Health Institute (PHI), and the UCLA Center for Health Policy Research (UCLA), the survey is largely funded by California sources. The 2000 CHIS CCM is similar in content to the 2000 NHIS CCM, and met its target of one sample adult in 55,000 households. California, the most populous state in the nation, is also the most racially and ethnically diverse. Specific populations of interest include Black or African American, Hispanic or Latino, Asian, Native Hawaiian or Other Pacific Islander, and American Indian or Alaska Native. The CHIS data was released in July 2002. NCI is using the CHIS and NHIS data from 2000/2001 to better estimate health-related behaviors and cancer risk factors for smaller racial/ethnic minority populations. Preliminary analyses suggest that the CHIS will provide improved estimates for cancer risk factors and screening among racial/ethnic minority populations. NCI will sponsor questions on cancer screening in the 2003 NHIS and to provide better estimates for smaller racial-ethnic minority populations, anticipates also sponsoring cancer-screening questions on the 2003 CHIS. NCI will also take advantage of the Housing and Environment Module to be included in the 2003 CHIS to ask respondents questions about environmental tobacco smoke and physical activity. *Frequency of response:* One-time. *Affected public:* Individuals. *Types of Respondents:* U.S. adults.

The annual reporting burden is as follows:

TABLE A.12-1.—ANNUALIZED BURDEN ESTIMATES FOR CHIS DATA COLLECTION

Data collection	Estimated number of respondents	Frequency of response	Average time per response	Annual hour burden
Adult Core	55,000	1	.42	23,100
CCM	55,000	1	.08	4,400
Totals	55,000			27,500

failure to comply with applicable laws or an existing corporate integrity agreement, regardless of the financial impact on Federal health care programs.

¹⁸ The OIG has published criteria setting forth those factors that the OIG takes into consideration in determining whether it is appropriate to exclude an individual or entity from program participation

pursuant to 42 U.S.C. 1320a-7(b)(7) for violations of various fraud and abuse laws. See 62 FR 67392 (December 24, 1997).

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.

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 Nancy Breen, PhD, Project Officer, National Cancer Institute, EPN 4005, 6130 Executive Boulevard MSC 7344, Bethesda, Maryland 20892-7344, or call non-toll-free number (301) 496-8500, or FAX your request to (301) 435-3710, or E-mail your request, including your address, to breenn@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: September 25, 2002.

Reesa L. Nichols,

NCI Project Clearance Liaison.

[FR Doc. 02-25089 Filed 10-2-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

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 meetings.

The meetings 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 person privacy.

Name of Committee: Training Grant and Career Development Review Committee.

Date: October 9-11, 2002.

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

Agenda: To review and evaluate grant applications.

Place: Monarch Hotel, 2400 M Street, NW., Washington, DC 20037.

Contact Person: Raul A. Saavedra, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223.

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.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders C.

Date: October 21-22, 2002.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Washington, 515 15th Street, NW., Washington, DC 2004.

Contact Person: Andrea Sawczuk, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, Bethesda, MD 20892-9529, 301-496-0660.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group, Neurological Sciences and Disorders A.

Date: October 24-25, 2002.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Madison Hotel, 15th and M Streets, NW., Washington, DC 20005.

Contact Person: Richard D. Crosland, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group, Neurological Sciences and Disorders K.

Date: October 24-25, 2002.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Katherine M. Woodbury, Ph.D., Scientific Review Administrator,

Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group, Neurological Sciences and Disorders B.

Date: October 24-25, 2002.

Time: 8:30 a.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: W. Ernest Lyons, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-4056.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: September 26, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-25090 Filed 10-2-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 on Drug Abuse Special Emphasis Panel; "Rodent and Monkey Testing for NIDA Medication Discovery Programs".

Date: October 17, 2002.

Time: 9:30 a.m. to 12 p.m.

Agenda: To review and evaluate contract proposals.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Rockville, MD 20852. (Telephone Conference Call).