

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

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: Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial.

Type of Information Collection Request: EXTENSION, OMB control number 0925-0407, expiration date July 31, 2005.

Need and Use of Information Collection: This trial is designed to determine if screening for prostate, lung, colorectal and ovarian cancer can reduce mortality from these cancers which currently cause an estimated 263,000 deaths annually in the U.S. The design is a two-armed randomized trial of men and women aged 55 to 74 at entry. The total sample size is 154,938. The primary endpoint of the trial is cancer-specific mortality for each of the four cancer sites (prostate, lung, colorectum, and ovary). In addition, cancer incidence, stage shift, and case survival are to be monitored to help understand and explain results. Biologic prognostic characteristics of the cancers will be measured and correlated with mortality to determine the mortality predictive value of these intermediate endpoints. Basic demographic data, risk factor data for the four cancer sites and screening history data, as collected from all subjects at baseline, will be used to assure comparability between the

screening and control groups and make appropriate adjustments in analysis. Further, demographic and risk factor information may be used to analyze the differential effectiveness of screening in high versus low risk individuals.

Frequency of Response: On occasion.

Affected Public: Individuals or households.

Type of Respondents: Adult men and women.

The annual reporting burden is as follows:

Estimated Number of Respondents: 145,852;

Estimated Number of Responses Per Respondent: 1.14;

Average Burden Hours Per Response: 0.14; and

Estimated Total Annual Burden Hours Requested: 23,278.

The annualized cost to respondents is estimated at: \$232,780. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated annual number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adults	145,852	1.14	0.14	23,278

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 Dr. Christine D. Berg, Chief, Early Detection Research Group, National Cancer Institute, NIH, EPN Building, Room 3070, 6130 Executive Boulevard, Bethesda, MD 20892, or call non-toll-free number 301-496-8544 or e-mail your request,

including your address to: BERGC@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: January 10, 2005.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Workplace Helpline Call Record Form (OMB NO. 0930-0232)—Revision

Workplace Helpline is a toll-free, telephone consulting service which provides information, guidance and assistance to employers, community-based prevention organizations and labor offices on how to deal with alcohol and drug abuse problems in the workplace. The Helpline was required by Presidential Executive Order 12564 and has been operating since 1987. It is located in the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Prevention (CSAP), where it is managed out of the Division of Workplace Programs.

Callers access the Helpline service through one of its Workplace Prevention Specialists (WPS) who may spend from several to up to 30 minutes with a caller, providing guidance on how to develop a comprehensive workplace prevention program (written policy, employee assistance program services, employee education, supervisor training, and drug testing) or components thereof.

When a call is received, the WPS uses a Call Record Form to record information about the call, including the name of the company or organization,

the address, phone number, and the number of employees. Each caller is advised that their responses are completely voluntary, and that full and complete consultation will be provided by the WPS whether or not the caller agrees to answer any question. To determine if the caller is representing an employer or other organization that is seeking assistance in dealing with

substance abuse in the workplace, each caller is asked for his/her position in the company/organization and the basis for the call. In the course of the call, the WPS will try to identify the following information: basis or reason for the call (*i.e.*, crisis, compliance with State or Federal requirements, or just wants to implement a prevention program or initiative); nature of assistance

requested; number of employees and whether the business has multiple locations; and the industry represented by the caller (*e.g.*, mining, construction, etc.). Finally, a note is made on the Call Record Form about what specific type(s) of technical assistance was given.

Below is the annual burden for the Helpline Call Record Form.

Form	Number of respondents	Responses/respondent	Burden/response (hrs.)	Total burden (hrs.)
Call Record Form	3,120	1	.250	780

Written comments and recommendations concerning the proposed information collection should be sent by February 23, 2005 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: (202) 395-6974.

Dated: January 13, 2005.

Anna Marsh,

Executive Officer, SAMHSA.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these

documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Survey of Medicaid Directors Regarding Medicaid Mental Health Services and Policy—New

The Substance Abuse and Mental Health Services Administration (SAMHSA) will conduct a survey of State Medicaid directors to learn about the relationships between State mental health authorities and State Medicaid agencies in each State and the District of Columbia. In addition, SAMHSA will ask about the administration of Medicaid mental health services, the development of Medicaid mental health policy, mental health services statistics generated by Medicaid programs, and the characteristics of mental health-related data maintained by Medicaid agencies and used by mental health and other state agencies.

The survey will contact State Medicaid directors in all fifty States (and the District of Columbia) and will gather information on the following five survey domains: Organization structure; Medicaid mental health services policy infrastructure; Medicaid mental health services, rates, and funding; Medicaid mental health providers; and, Data.

The survey will identify and describe, at the State level, how Medicaid mental health policy is developed; whether Medicaid mental health services and providers are treated differently from other Medicaid services and providers, and if so, how; and the availability of

data and reports on Medicaid mental health service use/and or expenditures.

This information collection supports the New Freedom Initiative, one of SAMHSA's current priorities. As part of this effort, the President launched the New Freedom Commission on Mental Health to address the problems in the current mental health system. The Commission noted that fragmentation of responsibility for mental health services is a serious problem at the State level. Two of the Commission's 19 recommendations for the improvement of the mental health system were aimed at this problem. One was directed to States (create a comprehensive State mental health plan) and the other to the Federal government (align relevant Federal programs to improve access and accountability for mental health services). This survey is aimed at providing information that can help in carrying out these recommendations by further illuminating the relationships between State Medicaid and mental health agencies in the development and implementation of mental health policy.

Telephone interviews will be conducted with State Medicaid directors. Each interview will last one hour. Because of the open-ended nature of many of the survey questions and the general reluctance of State Medicaid directors to complete detailed paper or electronic surveys, we propose to conduct all the interviews by telephone, unless interviewees prefer to respond to a paper or electronic version.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Number of respondents	Responses per respondent	Hours per response	Total hour burden
51	1	1	51

Written comments and recommendations concerning the proposed information collection should

be sent by February 23, 2005, to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office

of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential