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 t 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,