

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**National Institutes of Health**
**Submission for OMB Review; Comment Request; Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) (NCI)**

**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 to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 20, 2011 (76 FR 22108) and allowed 60 days for public comment. One public comment was received on April 20, 2011 which commented on the government spending money to support NIH. An email response was sent on May 18, 2011 stating, "Thank you for your comments and we will take it under advisement." 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:* Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) (NCI). *Type of Information Collection Request:* Revision (OMB #: 0925-0407, current expiry date 10/31/2011). *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 254,570 deaths annually in the U.S. The design is a two-armed randomized trial of men and women aged 55 to 74 at entry. OMB first approved this study in 1993 and has approved it every 3 years since then through 2011. During the first approval period a pilot study was conducted to evaluate recruitment methods and data collection procedures. Recruitment was completed in 2001 and data collection continues through 2014. When participants enrolled in the trial they agreed to be followed for at least 13 years from the time of enrollment. The current number of respondents in the

study is 122,655; this is down from the initial total due to deaths. The primary endpoint of the trial is cancer specific mortality for each of the four cancer sites (prostate, lung, colorectal, 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:* Annually. *Affected Public:* Individuals. *Type of Respondents:* Adult men and women. The annual reporting burden is provided for each study component as shown in the Table 1 below. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

**TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS**

Type of respondents	Survey instrument	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Male and Female Participants .....	ASU .....	92,941	1.00	5/60 (0.08)	7,745
	HSQ .....	2,000	1.00	5/60 (0.08)	167
	SQX .....	92,941	1.00	30/60 (0.50)	46,471
Total .....	.....	.....	.....	.....	54,383

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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 comments 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 Attention: NIH Desk Officer, Office of Management and Budget, at [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. 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 3100, 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](mailto:bergc@mail.nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: July 7, 2011.

**Vivian Horovitch-Kelley,**

*NCI Project Clearance Liaison, National Institutes of Health.*

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