[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; comment Request

Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) (NCI)

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 (PLCO) (NCI). *Type of Information Collection Request:* Revision (OMB #: 0925–0407, current expiration date 9/30/2014). *Need and Use of Information Collection:* This trial was designed to determine if cancer screening for prostate, lung, colorectal, and ovarian cancer can reduce mortality from these cancers which currently cause an estimated 255,700 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. The main change to this submission is that the Supplemental Questionnaire is being replaced with the Medication Use Questionnaire. As PLCO participants now range from 74-94 years of age, the focus is now on collecting additional information regarding medications that are particularly common among older adults. Additionally, the contracts for 8 of the 10 Screening Centers (SCs)

ended in 2011 and the remaining two sites will close in 2012 and 2014. NCI has awarded a contract for continuation of participant follow-up activities to one data collection site named the PLCO Central Data Collection Center (CDCC). In 2011, participants were re-consented for at least an additional five years of follow-up. The current number of respondents is limited to the approximately 94,000 participants being actively followed up. The reports on cancer screening and prostate, lung, colorectal, and ovarian cancer mortality based on this trial have been published in peer review medical journals. The additional follow-up will provide data that will clarify further the long term effects of the screening on cancer incidence and mortality for the four targeted cancers. Further, demographic and risk factor information may be used to analyze the differential effectiveness of cancer 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	94,000	1.00	5/60	7,833
	Script for ASU Non-response	3,760	1.00	5/60	313
	HSQ	2,000	1.00	5/60	167
	MUQ	94,000	1.00	15/60	23,500
Total					31,813

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) 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.

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 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.

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: July 10, 2012

Vivian Horovitch-Kelley

NCI Project Clearance Liaison

National Institutes of Health

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