



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day 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 Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on April 21, 2015 (80 FR 22211), and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), 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.

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: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT 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.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Kelly Yu, PhD, Division of Cancer Prevention, 9609 Medical Center Drive, Room 5E230, Rockville, MD 20850 call non-toll-free number 240-276-7041 or E-mail your request, including your address to: yuke@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) 0925-0407, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a request for a revision of the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO). This trial was designed to determine if cancer screening for prostate, lung, colorectal, and ovarian cancer can reduce mortality from these cancers which caused an estimated 253,320 deaths in the U.S in 2014. 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. Recruitment was completed in 2001, baseline cancer screening was completed in 2006, and data collection continues on the current cohort of 77,281 participants who are actively being followed. 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.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 26,320.

Estimated Annualized Burden Hours

| Form Name | Type of Respondents | Number of Respondents | Number of Responses per Respondent | Average Time Per Response (Minutes/Hour) | Annual Burden Hours |
|--|--|-----------------------|------------------------------------|--|---------------------|
| Annual Study Update(ASU) Form | Participants who complete the ASU | 77,281 | 1 | 5/60 | 6,440 |
| ASU Telephone Script | Non Responders to the ASU | 3,091 | 1 | 5/60 | 258 |
| Authorization to Release Medical Records | Participants who report new cancers | 2,700 | 1 | 3/60 | 135 |
| Health Status Questionnaire (Female) (HSQ) | Female participants who complete the HSQ | 960 | 1 | 5/60 | 80 |
| Health Status Questionnaire (Male) (HSQ) | Male participants who complete the HSQ | 1,040 | 1 | 5/60 | 87 |
| Medication Use Questionnaire (MUQ) | Participants who complete the MUQ | 77,281 | 1 | 15/60 | 19,320 |

Dated: June 23, 2015.

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NCI Project Clearance Liaison

National Institutes of Health

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