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TO: Office of Management and Budget (OMB)

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From: Christine Berg MD Principal Investigator, PLCO Cancer Screening Trial
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Subject: Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial
OMB#: 0925-0407

This is a request for OMB to approve a revision of the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (OMB No. 0925-0407) which currently expires on 10/31/2008. OMB first approved the PLCO Trial in October 1993 and then subsequently in 1996, 1999, 2002 and 2005. During the first approval period a pilot study was conducted to evaluate recruitment methods and data collection procedures. Recruitment was completed in 2001 with 154,938 participants recruited into the study. Each participant will be followed for at least 13 years from randomization. During this next approval period PLCO participants will be followed for cancer and vital status ascertainment.

The purpose of the PLCO Trial is to determine if screening for prostate, lung colorectal, and ovarian cancers aids in reducing mortality from these diseases. Men and women 55-74 years old were recruited into the study at 10 sites nationwide. Half of the participants were randomized into the screening cohort in which they received annual screening examinations for the 4 targeted cancer sites. The specific screening modalities being evaluated include: screening with chest x-ray for lung cancer; screening with flexible sigmoidoscopy for colorectal cancer; screening with digital rectal examination and PSA blood test for prostate cancer; and screening with transvaginal ultrasound and CA-125 blood test for ovarian cancer. The screening component of the study is now complete. The participants who are not randomized into the screening cohort follow their normal routine health care.

Participants in both cohorts will complete an Annual Study Update (ASU) questionnaire, Health Screening Questionnaire (HSQ), and a Prostate Cancer Recurrence Questionnaire (PCRQ). All subjects also provide annual health status information. If cancer is reported, diagnosis and treatment information is collected through abstracting medical records. Deaths are ascertained through the annual follow-up process.

It is the mission of the Early Detection Research Group of the NCI to conduct research into cancer prevention and control. The PLCO Cancer Screening Trial represents a major effort to determine the effectiveness of screening as a means of preventing cancer deaths.