



DATE: June 10, 2011

TO: Christine D. Berg, M.D., Project Officer
National Cancer Institute

FROM: NIH Privacy Act Officer

SUBJECT: Applicability of the Privacy Act: "Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) (NCI)"

I have reviewed the NCI submission to OMB to continue the collection of data for the PLCO Screening Trial to evaluate the effect of screening on the reduction of cancer specific mortality from four targeted sites. NCI seeks to increase the value of PLCO as a resource to intra- and extramural researchers by continuing to collect follow up behavioral data, morbidity and mortality outcomes and tumor tissue using one, rather than ten data collection centers.

I have determined that the Privacy Act will apply to this data collection which involves the collection of personally identifiable information such as participant name, participant ID, date of birth, social security number (SSN), telephone number, current marital status, religion at birth, ethnicity, race, etc. Basic demographic, socioeconomic, occupational, and risk factor information collected from the participants at baseline will be used to assure comparability between the screening and control groups and stored in a database. For subsequent annual information collections, information previously supplied by the participant is pre-populated and sent to him/her for confirmation (e.g., name and address of primary care physician and tracing contacts).

All completed hard copy data forms are kept in locked filing facilities. Data collected in automated information systems are physically separate from other institutional systems. Access to files is through the use of a password known only to authorized staff. Names and SSNs are encrypted and stored in files separate from other data and linked only by the participant ID. Data collected are maintained until the study is completed or until no longer required for research.

This data collection is covered by NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of National Institutes of Health (NIH), HHS/NIH/OD."

If you have any questions, please contact my office at (301) 402-6201.

A handwritten signature in cursive script, appearing to read "Karen M. Plá".

Karen M. Plá

cc: Vivian Horovitch-Kelley, PRA/OMB Project Clearance Liaison