



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

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To: Office of Management and Budget (OMB)

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National Cancer Institute (NCI)/NIH

Subject: Resource for the Collection and Evaluation of Human Tissues and Cells from Donors with an Epidemiology Profile (NCI)

This is a request for OMB to approve the new information collection titled, "Resource for the Collection and Evaluation of Human Tissues and Cells from Donors with an Epidemiology Profile" for three years of data collection. These cohort studies will obtain personal histories, life styles and environmental exposures of population controls to compare to those of patients in prospective, case-control studies of the environment, molecular epidemiology and lung, prostate and liver cancers in the region. In addition to questionnaires, the patients and the controls will provide biospecimen samples that receive identical tests for comparisons. This design allows the continuing study of how health and lifestyle behaviors may relate to societal and environmental contributions of the cause, progression, and therapeutic responses of the cancers under study.

A listing of 687,902, drivers (from Maryland's Motor Vehicles Administration), provided by the contractor (whom the State grants access for research purposes) form the cohort of potential participants periodically selected from to be matched (by age, race, gender and location) to cancer patients and asked to volunteer. The annualized burden for the completion of the questionnaires by an expected 200 respondents is 300 hours.

The studies are conducted in Baltimore, Maryland and the surrounding Counties and supported by the University of Maryland Hospital Medical Center, the Baltimore Veteran Administration Hospital, and Johns Hopkins University Hospital (including the Bay View Subsidiary). Controls will be recruited via NCI contract # NO2-RC-57700 held by The University of Maryland Medical School at Baltimore. The patient portion of these studies have been granted Clinical Exemption by NIH (10/28/09: #2009-09-002).

A mission of the NCI is to study the cause, detection, diagnosis, prevention and treatment of cancer resulting from occupational and environmental exposures and this project supports and furthers NCI's ability to achieve these objectives.